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Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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[CMS–1159–F2]

RIN 0938–AK54

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and changes arising from our continuing experience with this system. In addition, it describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. This final rule also announces a uniform reduction of 68.9 percent to be applied to each of the transitional pass-through payments. These changes are applicable to services furnished on or after January 1, 2002.

EFFECTIVE DATE: This final rule is effective January 1, 2002 and is applicable to services furnished on or after January 1, 2002.

FOR FURTHER INFORMATION CONTACT: George Morey (410) 786–4653, for provider-based issues; and Nancy Edwards (410) 786–0378, for all other issues.

SUPPLEMENTARY INFORMATION:

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Information on the outpatient prospective payment system can be found on our homepage. You can access these data by using the following directions:

1. Go to CMS homepage (*http://www.cms.hhs.gov*).
2. Click on ''Professionals.''
3. Under the heading ''Physicians and Health Care Professionals,'' click on ''Medicare Coding and Payment Systems.''
4. Select Hospital Outpatient Prospective Payment System.

Or, you can go directly to the Hospital Outpatient Prospective Payment System page by typing the following: *http://www.hcfa.gov/medicare/hopsmain.htm.*

To assist readers in referencing sections contained in this document, we are providing the following table of contents.

Outline of Contents

Alphabetical List of Acronyms Appearing in the Proposed Rule

APC Ambulatory payment classification
APG Ambulatory patient group
ASC Ambulatory surgical center
AWP Average wholesale price
BBA 1997 Balanced Budget Act of 1997
BBRA 1999 Balanced Budget Refinement Act of 1999
BIPA 2000 Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAH Critical access hospital
CAT Computerized axial tomography
CCI Correct Coding Initiative
CCR Cost-to-charge ratio
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services (Formerly known as the Health Care Financing Administration)
CORF Comprehensive outpatient rehabilitation facility
CPI Consumer Price Index
CPT (Physician's) Current Procedural Terminology, Fourth Edition, 2001, copyrighted by the American Medical Association
DME Durable medical equipment
DMEPOS DME, prosthetics (which include prosthetic devices and implants), orthotics, and supplies
DRG Diagnosis-related group
EMTALA Emergency Medical Treatment and Active Labor Act
FDA Food and Drug Administration
FQHC Federally qualified health center
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
ICD–9–CM International Classification of Diseases, Ninth Edition, Clinical Modification
IME Indirect medical education
JCAHO Joint Commission on Accreditation of Healthcare Organizations
MRI Magnetic resonance imaging
MSA Metropolitan statistical area
NECMA New England County Metropolitan Area
OPPS Hospital outpatient prospective payment system
PPS Prospective payment system
RFA Regulatory Flexibility Act
RHC Rural health clinic
RRC Rural referral center
SCH Sole community hospital
SNF Skilled nursing facility

I. Background

A. Authority

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000, made further changes in the OPPS. The BIPA provisions that affect the OPPS are summarized below, in section I.C. The OPPS was first implemented for services furnished on or after August 1, 2000.

B. Summary of Rulemaking

- On September 8, 1998, we published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.
- On April 7, 2000, we published a final rule with comment period (65 FR 18438) that addressed the provisions of the PPS for hospital outpatient services scheduled to be effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition, this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA of 1997 and amended by the BBRA of 1999. Medicare regulations governing the hospital OPPS are set forth at 42 CFR 419.
- On June 30, 2000, we published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000.
- On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.
- On November 13, 2000, we published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.
- On August 24, 2001, we published a proposed rule (66 FR 44672) that set forth proposed changes to the Medicare hospital OPPS and calendar year (CY) 2002 payment rates. It also set forth proposed changes to the amounts and factors used to determine these payment rates.

C. Summary of Changes in the August 24, 2001 Proposed Rule

On August 24, 2001, we published a proposed rule (66 FR 44672) that set forth proposed changes to the Medicare hospital OPPS and CY 2002 payment rates including changes to the amounts and factors used to determine these payment rates.

The following is a summary of the major changes that we proposed and the

issues we addressed in the August 24, 2001 proposed rule.

1. Changes Required by BIPA 2000

We proposed the following changes to the OPPS, to implement the provisions of BIPA 2000:

- Limit coinsurance to a specified percentage of APC payment amounts.
- Provide hold-harmless payments to children's hospitals.
- Provide separate APCs for services that use contrast agents and those that do not.
- Payment for glaucoma screening as a covered service.
- Payment for certain new technology used in diagnostic mammograms.

2. Additional Changes

We proposed the following additional changes to the OPPS:

- Add APCs, delete APCs, and modify the composition of services within some existing APCs.
- Add an APC group that would provide separate payment for observation services in limited circumstances to patients having specific diagnoses.
- Recalibrate the relative payment weights of the APCs.
- Update the conversion factor and wage index.
- Revise the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights and the other required updates and adjustments.
- Make reductions in pass-through payments for specific drugs and categories of devices to account for the drug and device costs that are included in the APC payment for associated procedures and services.
- Apply a standard procedure to calculate copayment amounts when new APCs are created or when APC payment rates are increased or decreased as a result of recalibrated relative weights.
- Calculate outlier payments on a service-by-service basis beginning in 2002. We also proposed a methodology for allocating packaged services to individual APCs in determining costs of a service and we proposed to use a hospital's overall outpatient cost-to-charge ratio to convert charges to costs.
- Set the threshold for outlier payments to require costs to exceed 3 times the APC payment amount and payment at 50 percent of any excess costs above the threshold.
- Exclude hospitals located outside the 50 states, the District of Columbia and Puerto Rico from the OPPS.
- Exclude from payment under the OPPS certain services that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.
- Make conforming changes to regulations text to reflect the exclusion from the OPPS of certain items and services (for example, bad debts, direct medical education and certain certified registered nurse anesthetists services) that are paid on a cost basis.
- Update the payments for pass-through radiopharmaceuticals, drugs, and biologicals on a calendar year basis to reflect increases in AWP.
- Allow reprocessed single use devices to be considered eligible for pass-through payments if the reprocessing process for single use devices meets the FDA's most recent criteria.
- Revise the criteria we will use to determine whether a procedure or service is eligible to be assigned to a new technology APC.
- Revise the list of information that must be submitted to request assignment of a service or procedure to a new technology APC.
- Provide more flexibility in the amount of time a service may be paid under a new technology APC.
- A description of the Secretary's estimate of the total amount of pass-through payments for CY 2002 and the need for a pro rata reduction to those payments in that year.

3. Provider-Based Changes

We proposed to make changes to the provider-based regulations to reflect the provisions of section 404 of BIPA and to codify certain clarifications on provider-based status that were posted on the CMS Web site.

D. Public Comments Received in Response to the August 24, 2001 Proposed Rule

We received approximately 400 timely items of correspondence containing multiple comments on the proposed rule. Major issues addressed by the commenters included the following:

- The implementation of a uniform reduction in the transitional pass-through payments for CY 2002.
- Changes to APC classifications and weights for certain outpatient services including mammography, stereotactic radiosurgery and intensity modulated radiation therapy, and positive emission tomography (PET) scans.
- Changes to the eligibility criteria for payment as a new technology service.

On November 2, 2001, we published a final rule (66 FR 55857) that responded to the comments on the Secretary's estimate of the total amount of transitional pass-through payments for CY 2002 and the need for a uniform reduction in the pass-through payments for that year as well as comments on the proposed conversion factor for CY 2002. That final rule announced that the conversion factor for CY 2002 is $50.904 and that the Secretary is implementing a pro rata reduction in 2002 (expected to be between 65 and 70 percent) to each pass-through payment (we stated that we would announce the exact amount of the reduction before the beginning of 2002).

Summaries of the remaining public comments received and our responses to those comments are set forth below under the appropriate heading. In addition, we are announcing that the pro rata reduction is 68.9 percent.

II. Changes to the APC Groups and Relative Weights

Under the OPPS, we pay for hospital outpatient services on a rate per service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 0601, Mid-Level Clinic Visits. As described in the April 7, 2000 final rule (65 FR 18484), the APC weights are scaled to APC 0601 because a mid-level clinic visit is one of the most frequently performed services in the outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review the components of the OPPS not less often than annually and to revise the groups and related payment adjustment factors to take into account changes in medical practice, changes in technology, and the addition of the new services, new cost data, and other relevant information. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 2001, to consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights.

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median or mean cost item or service in the group is more than 2 times greater than the lowest median or mean cost item or service within the same group (referred to as the ''2 times rule''). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule ''in

unusual cases, such as low volume items and services.''

For the proposed rule and for this final rule, we analyzed the APC groups within this statutory framework.

A. Recommendations of the Advisory Panel on APC Groups

1. Establishment of the Advisory Panel

Section 1833(t)(9)(A) of the Act, which requires that we consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights, specifies that the panel will act in an advisory capacity. The expert panel, which is to be composed of representatives of providers, is to review and advise us about the clinical integrity of the APC groups and their weights. The Panel is not restricted to using our data and may use data collected or developed by organizations outside the Department in conducting its review.

On November 21, 2000, the Secretary signed the charter establishing an ''Advisory Panel on APC Groups'' (the Panel). The Panel is technical in nature and is governed by the provisions of the Federal Advisory Committee Act (FACA) as amended (Public Law 92–463). To establish the Panel, we solicited members in a notice published in the **Federal Register** on December 5, 2000 (65 FR 75943). We received applications from more than 115 individuals nominating either themselves or a colleague. After carefully reviewing the applications, CMS chose 15 highly qualified individuals to serve on the Panel. The Panel was convened for the first time on February 27, February 28, and March 1, 2001. We published a notice in the **Federal Register** on February 12, 2001 (66 FR 9857) to announce the location and time of the Panel meeting, a list of agenda items, and that the meeting was open to the public. We also provided additional information through a press release and our website.

2. Specific Recommendations of the Advisory Panel and Our Responses

In the proposed rule, we summarized the issues considered by the Panel, the Panel's APC recommendations, and our subsequent action with regard to the Panel's recommendations. The data used by the Panel in making its recommendation are the 1996 claims that were used to set the APC weights and payment rates for CY 2000 and 2001. In the proposed rule, we provided a detailed summary of the Panel discussion and recommendations (66 FR 44675–44686). See the proposed rule for more details regarding these discussions.

As discussed below, the Panel sometimes declined to recommend a change in an APC even though the APC violated the 2 times rule. In section II.C.3 of this preamble, we discuss our policies regarding the 2 times rule based on the data we are using to recalibrate the 2002 APC relative weights (that is, claims for services furnished on or after July 1, 1999 and before July 1, 2000). That section also details the criteria we use in deciding to make an exception to the 2 times rule. We asked the Panel to review many of the exceptions we implemented in 2000 and 2001. The exceptions are referred to as ''violations of the 2 times'' rule in the following discussion.

We did not receive comments on the APC changes we proposed based on the recommendations of the Panel except for our proposal regarding stereotactic radiosurgery (APCs 0300 and 0302). We discuss that proposal in detail below along with the comments and our responses. For all other APC Panel proposed changes, we briefly discuss the Panel's recommendation, our proposal, and the final changes we have made. We also received comments on APCs and the assignment of codes to APCs for which we made no specific proposal in the proposed rule. We address those comments below in section II.A.3. of this preamble.

APC 0016: Level V Debridement & Destruction

APC 0017: Level VI Debridement & Destruction

We asked the Panel to review the current placement of CPT code 56501, Destruction of lesion(s), vulva; simple, any method, in APC 0016 because the APC violates the 2 times rule. Because the procedure is a simple destruction of skin and superficial subcutaneous tissues, we will not expect it to have a median cost of $500. Thus, we believe that the higher costs associated with this code were the result of incorrect coding. To ensure that procedures in APC 0016 comply with the 2 times rule, we asked the Panel to consider one of the following clinical options:

- Move CPT code 56501 to APC 0017.
- Retain CPT code 56501 in APC 0016 but split APC 0016 into three APCs to distinguish simple destruction lesions from extensive destruction lesions.

The Panel recommended the following:

- Move CPT code 56501 from APC 0016 to APC 0017.
- Move CPT code 46917 from APC 0014 to APC 0017.

After considerable discussion the Panel recommended these changes to achieve clinical coherence and resource similarity among the procedures assigned to these APCs. Because CPT code 46917 is performed using laser equipment and requires anesthesia, the Panel believed it appropriate to move this procedure to APC 0017. Although the Panel considered the reassignment of CPT code 54055 to APC 0017, it did not recommend this change. The Panel's recommended changes will group in APC 0017 simple destruction of lesion procedures that use laser or surgical techniques with extensive destruction of lesion procedures.

We proposed to accept the Panel's recommendation regarding CPT code 56501 and to revise the APC accordingly. We are adopting these changes in final; however, as shown below in Table 3, we are making additional changes to these APCs because of the 2 times rule.

APC 0024: Level I Skin Repair

APC 0025: Level II Skin Repair

APC 0026: Level III Skin Repair

APC 0027: Level IV Skin Repair

The composition of procedures in APCs 0025 and 0027 results in these APCs violating the 2 times rule. Therefore, we requested the Panel's advice in exploring other clinical options for reconfiguring the four skin repair APCs to achieve clinical and resource homogeneity among the procedures assigned to APCs 0025 and 0027 while retaining clinical and resource homogeneity for APCs 0024 and 0026. We asked the Panel to consider the following clinical options to achieve this result:

- Rearrange the procedures assigned to APCs 0024 through 0027 based on the size or the length of the skin incision.
- Rearrange the procedures assigned to APCs 0024 through 0027 based on the complexity of the repair, such as distinguishing repairs that involve layers of skin, flaps, or grafts from those that do not.

The Panel reviewed the various options presented, which were modeled based on the 1996 claims data used in constructing the current APC groups and payment rates. The Panel recommended the following:

- Make no changes to APCs 0024 and 0027.
- Reevaluate these APCs with new data when the Panel meets in 2002.
- The Panel, in preparation for the 2002 meeting, will discuss options with and gather clinical and utilization information from their respective hospitals regarding these procedures.

We proposed to accept the Panel's recommendations. We are adopting these recommendations as final; however, as discussed below in section II.C., we are making additional changes to these APCs based on the use of new data and application of the 2 times rule.

APC 0058: Level I Strapping and Casting Application

APC 0059: Level II Strapping and Casting Application

APC 0058 (which consists of the simpler casting, splinting, and strapping procedures) violates the 2 times rule. The median costs for high volume procedures in APC 0058 vary widely, ranging from $27 to $83. The median costs associated with presumably more resource-intensive procedures in APC 0059 are fairly uniform, ranging from $69 to $119. To limit the cost variation in APC 0058, we asked the Panel to consider the following options:

- Move the following four codes from APC 0058 to APC 0059: CPT code 29515, Application of short splint (calf to foot); CPT code 29520, Strapping; hip; CPT code 29530, Strapping; knee; and CPT code 29590, Denis-Brown splint strapping.
- Create a new APC to include a third level of strapping and casting application procedures by regrouping all procedures assigned to both APCs 0058 and 0059 based on the following clinical distinctions: removal/revision, strapping/splinting, and casting.
- Package certain CPT codes assigned to APC 0058 with relevant procedures.

The Panel recommended that we do the following:

- Make no changes to APC 0058.
- Provide appropriate education and guidance to hospitals regarding appropriate use and billing of codes in APC 0058.
- Resubmit APC 0058 to the Panel for reevaluation when later data are available.

We proposed to accept the Panel's recommendations except that we proposed to move CPT code 29515 to APC 0059 due to the 2 times rule and the newer data we are using for this rule. These changes have been adopted as final in this document.

APC 0079: Ventilation Initiation and Management

The codes in APC 0079 represent respiratory treatment and support provided in the outpatient setting. The cost variation among the assigned procedures in this APC raises concern about hospital coding practices. The median costs for these procedures range from $40 to $315. We asked the Panel to clarify whether these procedures are performed on outpatients or if they are performed on patients who come to the emergency room and are later admitted to the hospital as inpatients.

The Panel recommended the following:

- Remove CPT code 94660 from APC 0079 and create a new APC for this one procedure.

We proposed to accept the Panel's recommendation by creating a new APC 0065, CPAP Initiation. We have adopted this change in this final rule.

APC 0094: Resuscitation and Cardioversion

We requested the Panel's assistance in determining whether it is clinically appropriate to remove the cardioversion procedures from APC 0094 because the rest of the procedures assigned to APC 0094 are emergency procedures rather than elective. We proposed that the Panel consider the creation of a new APC for the cardioversion procedures or reassignment of the procedures to another APC that would be more appropriate in terms of clinical coherence and resource similarity. Splitting APC 0094 into two distinct groups, one for resuscitation procedures and the other for internal and external electrical cardioversion procedures, would not result in a significant difference in the APC payment rate for either of the new APCs.

The Panel recommended that the only action we take would be to move CPT code 92961, Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure) from APC 0094 to APC 0087, Cardiac Electrophysiology Recording/Mapping.

We proposed to accept the APC Panel recommendation. We are adopting this change as final.

APC 0102: Electronic Analysis of Pacemakers/Other Devices

The neurologic procedures included in APC 0102 (CPT codes 95970 through 95975), are significantly more complex than the routine cardiac pacemaker programming codes also assigned to this APC. Because we believe these codes are clinically different, we asked the Panel to consider the following:

- Create a new APC for the neurologic codes.
- Move the neurologic codes to APC 0215, Level I Nerve and Muscle Tests.

The Panel recommended the following reorganization of APC 0102 to better reflect clinical coherence:

- Split APC 0102 into four new APCs: one APC for analysis and programming of infusion pumps and CSF shunts; a second for analysis and programming of neurostimulators; a third for analysis and programming of pacemakers and internal loop recorders; and a fourth for analysis and programming of cardioverter-defibrillators.

We proposed to accept the Panel's recommendations and proposed to create four new APCs as follows:

APC 0689: Electronic Analysis of Cardioverter-Defibrillator
APC 0690: Electronic Analysis of Pacemakers and Other Cardiac Devices
APC 0691: Electronic Analysis of Programmable Shunts/Pumps
APC 0692: Electronic Analysis of Neurostimulator Pulse Generators.

We have made these changes final in this rule.

APC 0110: Transfusion

APC 0111: Blood Product Exchange

APC 0112: Extracorporeal Photopheresis

The procedures included in APC 0110 are those related only to the services associated with performing the blood transfusion and monitoring the patient during the transfusion; the costs associated with the blood products themselves are not included in APC 0110. We advised the Panel that we were not certain that cost data for blood transfusions excluded the costs of the blood products because the APC 0110 median cost of $289 seemed excessive. We expressed concern about hospital coding and billing practices for blood products, blood processing, storage, and transportation charges as represented in the 1996 data. We asked the Panel to advise us on how to clarify hospital billing and coding practices for blood transfusions; we also asked if the Panel members believe that the median costs for transfusion procedures include the costs for blood products and, if so, how the procedures should be adjusted to eliminate these costs.

After considerable discussion, the Panel recommended the following:

- Take no action on APC 0110.
- Move CPT code 36521 from APC 0111 to APC 0112 to achieve clinical coherence and resource similarity with photopheresis procedures included in APC 0112. However, the Panel cautioned that the payment for APC 0112 captured the cost of the entire procedure including the cost of the adsorption column. For this reason, any additional payment for the adsorption column through the transitional pass-through payment mechanism will be a duplicate payment. Therefore, the Panel asked that CMS address this problem when considering their recommendation.

We proposed to accept the Panel's recommendations. We noted that effective April 1, 2001, the Prosorba column is no longer eligible for a transitional pass-through payment (see PMA–01–40 issued on March 27, 2001).

We have adopted the proposed changes in final in this document.

APC 0116: Chemotherapy Administration by Other Technique Except Infusion

APC 0117: Chemotherapy Administration by Infusion Only

APC 0118: Chemotherapy Administration by Both Infusion and Other Technique

Based on previous comments we had received, we asked the Panel to review whether oral delivery of chemotherapy and delivery of chemotherapy by infusion pumps and reservoirs should be recognized for payment under the OPPS.

In summary, the Panel recommended the following:

- Allow hospitals to bill for patient education on the administration of oral anticancer agents under the appropriate clinic codes.
- Assign CPT codes 96520 and 96530 to a new APC.
- Continue to use the current HCPCS Level II Q codes for chemotherapy administration.
- There is no need to develop a new HCPCS code for ''extended chemotherapy infusions.''
- CMS should consider developing a new HCPCS code for flushing of ports and reservoirs.

We proposed to accept all the Panel's recommendations except for the recommendation regarding flushing of ports and reservoirs. Flushing is performed in conjunction with either a chemotherapy administration service or an outpatient clinic visit. In the first case, flushing is part of the chemotherapy administration and its costs are adequately captured in the costs of the chemotherapy administration code. In the second case, we believe that the costs of flushing are adequately captured in the costs of the clinic visit and need not be paid separately. We proposed to create a new APC 0125, Refilling of Infusion Pump.

We are adopting these changes as final in this rule.

APC 0123: Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant

In APC 0123, the 1996 median cost for CPT code 38230, Bone marrow harvesting for transplantation, was only $15. We believe that this cost is lower than the actual cost of the procedure. Further, we do not have sufficient data to determine how often bone marrow and stem cell transplant procedures are performed on an outpatient basis. For these reasons, we requested the Panel's advice in clarifying the resources used in performing the procedures assigned to APC 0123, and the extent to which these procedures are performed on an outpatient basis.

The Panel recommended the following:

- Make no changes in the procedures assigned to APC 0123 in the absence of sufficient data to support such modifications.
- The two presenters on this APC issue should submit cost data for the Panel to use in reevaluating this issue at its 2002 meeting.

We noted in the proposed rule that our analysis of the more recent claims data we are using to reclassify and recalibrate the APCs reveals a significant increase in costs for this APC resulting in a payment rate that is double the current rate. However, very few procedures (fewer than 20) were billed on an outpatient basis. As we indicated in the proposed rule, we will have the Panel review this APC again at their next meeting.

APC 0142: Small Intestine Endoscopy

APC 0143: Lower GI Endoscopy

APC 0145: Therapeutic Anoscopy

APC 0147: Level II Sigmoidoscopy

APC 0148: Level I Anal/Rectal Procedures

APC 0149: Level II Anal/Rectal Procedures

APC 0150: Level III Anal/Rectal Procedures

We presented these seven APCs to the Panel because of the inconsistencies in the median costs for some procedures included in APCs 0142, 0143, 0145, and 0147. We advised the Panel that our cost data do not show a progression of median costs proportional to increases in clinical complexity as we would expect. For example, the data indicate that a therapeutic anoscopy assigned to APC 0145 costs more than twice as much as a flexible or rigid sigmoidoscopy assigned to APC 0147. We stated our concern that cost disparity could provide incentives to use inappropriate procedures. Because of these concerns, we asked the Panel's advice in determining whether one of the following actions should be taken:

- Divide the codes in APC 0142 into separate APCs representing ileoscopy and small intestine procedures.
- Combine diagnostic anoscopy and Level I sigmoidoscopy.
- Merge APCs 0143, 0145, and 0147 into one APC.

We also asked the Panel whether the costs associated with codes in APC 0145 appeared to be valid.

The Panel recommended that we do the following:

- Make no changes to APCs 0142, 0143, 0145, and 0147.
- Provide information and guidance to better assist hospitals in understanding how to bill appropriately for services included in APCs 0142, 0143, 0145, and 0147.
- Resubmit these APCs to the Panel for review when newer data are available.

We proposed to accept the Panel's recommendations.

We have adopted these recommendations in this final rule.

APC 0151: Endoscopic Retrograde Cholangio-Pancreatography (ERCP)

We advised the Panel that we have received comments that indicate that it is inappropriate to assign both diagnostic and therapeutic ERCP procedures to the same APC. The commenters allege that virtually every hospital performs diagnostic ERCPs but only teaching hospitals perform therapeutic ERCPs. Based on our current data, if we created two APCs for ERCP procedures, the APC payment rate for therapeutic ERCPs would be lower than that for diagnostic ERCPs (approximately $526 and $535, respectively). Therefore, we requested the Panel's advice to help us determine whether to create separate APCs for diagnostic and therapeutic ERCP procedures.

The Panel recommended that we do the following:

- Do not reconfigure the ERCP procedures in APC 0151.
- Resubmit this issue to the Panel for review when more recent data are available.
- Explore the feasibility of using multiple claims rather than single claims to calculate appropriate APC payment rates for ERCP procedures.

We proposed to accept the Panel's recommendations. As we stated in the proposed rule, we are reviewing the potential for using multiple claims data for determining payment rates for ERCP procedures. As a first step in the process, in the proposed rule, we determined a payment rate for ERCP procedures based on both single claims for ERCP procedures and, because ERCP procedures are typically done under radiologic guidance, on claims that included both an ERCP procedure and a radiologic supervision or guidance procedure in this APC. We

accomplished this by changing the status indicator for radiologic guidance and supervision codes to ''N'', which results in these codes being packaged. Using these additional claims resulted in significantly increasing the number of claims used to determine the payment rate for this APC and in a much higher payment rate (about $780 in this final rule).

We will be presenting this issue again to the APC Panel at their next meeting.

APC 0160: Level I Cystourethroscopy and other Genitourinary Procedures

APC 0161: Level II Cystourethroscopy and other Genitourinary Procedures

APC 0162: Level III Cystourethroscopy and Other Genitourinary Procedures

APC 0163: Level IV Cystourethroscopy and Other Genitourinary Procedures
APC 0169: Lithotripsy

We advised the Panel that we had previously received a number of comments that advocated moving CPT code 52337, Cystoscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included), from APC 0162 to APC 0163. (We note that CPT code 52337 was deleted for 2001 and replaced with an identical CPT code, 52353. We will use the new code in the following discussion.) Because of these comments, we sought the Panel's advice in examining the clinical and resource distinctions between CPT code 52353 and other procedures assigned to APC 0162. Other information shared with the Panel noted that most of the procedures included in APC 0162 are complicated cystourethroscopies while those assigned to APC 0163 are largely prostate procedures.

The Panel recommended that we move CPT code 52353 from APC 0162 to APC 0169 because both codes 52353 and 50590 are lithotripsy procedures.

We reviewed the Panel discussion very carefully and noted the close vote. After careful consideration, we proposed to disagree with the Panel's recommendation and move code 52353 to APC 0163. The 1999–2000 cost data used for the proposed rule, which contained over 400 single claims for code 52353 (reported under code 52337) and over 6,000 single claims for code 50590, showed that the median cost for code 52353 is much more similar to the median cost of other procedures in APC 0163 than it is to the median cost of APC 0169. Although both codes involve lithotripsy, the type of equipment used in the two procedures is very different. Clinically, the surgical approach used for code 52353 and the resources used (e.g., anesthesia and operating room costs) are much more similar to other procedures in APC 0163 than to those for code 50590. Additionally, the median cost for code 50590, which was $700 higher than that of code 52353, is dependent on the widely variable arrangements hospitals make for use of the extracorporeal lithotriptor. Therefore, we believe that placing code 52353 in APC 0163 maintains its clinical coherence and similar use of resources.

Based on the updated 1999–2000 data base available for the final rule, we find that the cost relationship between codes 52353 and 50590 continues to reflect a difference. There are now almost 500 single claims for code 52353 and almost 7,000 single claims for code 50590. The median cost for 50590 remains about $700 higher than the median cost for code 52353. Therefore, we are adopting as final our proposal to move code 52353 to APC 0163.

APC 0191: Level I Female Reproductive Procedures

APC 0192: Level II Female Reproductive Procedures

APC 0193: Level III Female Reproductive Procedures

APC 0194: Level IV Female Reproductive Procedures

APC 0195: Level V Female Reproductive Procedures

This group of APCs was presented to the Panel because APC 0195 violates the 2 times rule. To facilitate the Panel's review of this issue, we distributed cost data on all the female reproductive procedures assigned to these five APCs. These data showed that the median costs for procedures assigned to APC 0195 ranged from a low of $365 to a high of $1,817. The CPT code 57288, Sling operation for stress incontinence (e.g., fascia or synthetic), which is assigned to APC 0195, has the highest median cost of the procedures in this group. We discussed with the Panel two clinical options for rearranging the procedures assigned to APC 0195 to comply with the 2 times rule. The first option would split APC 0195 into two separate APCs by separating vaginal procedures from abdominal procedures. The second option would split APC 0195 into three distinct APCs by retaining the separate APCs for abdominal and vaginal procedures and further distinguishing vaginal procedures based on whether they are simple or complex.

The Panel closely reviewed the four APCs for female reproductive procedures (APCs 0191, 0192, 0193, and 0194) to ensure each was clinically homogeneous. As a result of this review, the Panel recommended a number of changes for these APCs. These recommendations and those for APC 0195 are as follows:

- Move CPT codes 56350, Hysteroscopy, diagnostic, and 58555, Hysterosocopy, diagnostic/separate procedure, from APC 0191 to APC 0194 (In 2001, CPT code 56350 was replaced with CPT code 58555.)
- Divide APC 0195 into two APCs to distinguish vaginal procedures from abdominal procedures.
- Retain the following vaginal procedures in APC 0195:

CPT code	Descriptor
57555 ..	Excision of cervical stump, vaginal approach: with anterior and/or posterior repair.
58800 ..	Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); vaginal approach.
58820 ..	Drainage of ovarian abscess; vaginal approach, open.
57310 ..	Closure of urethrovaginal fistula;
57320 ..	Closure of vesicovaginal fistula; vaginal approach
57530 ..	Trachelectomy (cervicectomy), amputation of cervix (separate procedure).
57291 ..	Construction of artificial vagina; without graft.
57220 ..	Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral plication).
57550 ..	Excision of cervical stump, vaginal approach.
57556 ..	Excision of cervical stump, vaginal approach; with repair of enterocele.
57289 ..	Pereyra procedure, including anterior colporrhapy.
57300 ..	Closure of rectovaginal fistula; vaginal or transanal approach.

CPT code	Descriptor
57284 ..	Paravaginal defect repair (including repair of cystocele, stress urinary incontinence, and/or incomplete vaginal prolapse).
57265 ..	Combined anteroposterior colporrhaphy; with enterocele repair.
57268 ..	Repair of enterocele vaginal approach (separate procedure).
56625 ..	Vulvectomy simple; complete.
58145 ..	Myomectomy excision of fibroid tumor of uterus, single or multiple (separate procedure); vaginal approach.
57260 ..	Combined anteroposterior colporrhaphy;
57240 ..	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele.
57250 ..	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy.
56620 ..	Vulvectomy simple; partial.
57522 ..	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; loop electrode excision.

• Include the following abdominal procedures in a new APC titled ''Level VI Female Reproductive Procedures.''

CPT code	Descriptor
58920 ..	Wedge resection or bisection of ovary, unilateral or bilateral.
58900 ..	Biopsy of ovary, unilateral or bilateral (separate procedure).
58925 ..	Ovarian cystectomy, unilateral or bilateral.
57288 ..	Sling operation for stress incontinence (e.g., fascia or synthetic).
57287 ..	Removal or revision of sling for stress incontinence (e.g., fascia or synthetic).

• Move CPT code 57107 from APC 0194 to APC 0195, Level V Female Reproductive Procedures.

• Move CPT code 57109, Vaginectomy with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), from APC 0194 to the new APC, Level VI Female Reproductive Procedures.

We proposed to accept all of these Panel recommendations. These APCs would be reconfigured and renumbered as APCs 0188 to 0194. We also proposed to add new APCs for Level VII and Level VIII Female Reproductive Procedures (APCs 0195 and 0202, respectively) based on the 1999–2000 claims data and the 2 times rule. These proposed changes have been adopted as final in this document.

APC 0210: Spinal Tap

APC 0211: Level I Nervous System Injections

APC 0212: Level II Nervous System Injections

The Panel heard testimony from two presenters regarding the merits of modifying these three APCs. The first presenter, speaking on behalf of a manufacturer, discussed a new code for 2001, CPT code 64614, Chemodenervation of muscles; extremities and/or trunk muscles (e.g., for dystonia, cerebral palsy, multiple sclerosis).

The second presenter, representing a specialty society, proposed regrouping the procedures assigned to APCs 0210, 0211, and 0212 based on similar levels of complexity and median costs. The presenter's proposal also included reassignment to these APCs of interventional pain procedures currently assigned to APCs 040, Arthrocentesis and Ligament/Tendon Injection, 0105, Revision/Removal of Pacemakers, AICD, or Vascular Device, and 0971. The presenter proposed establishing the following five levels of interventional pain procedures by regrouping the procedures into new APCs as stated below:

• Level I Nerve Injections (to include Trigger Point, Joint, Other Injections, and Lower Complexity Nerve Blocks):

CPT code	Reassigned from APC
20550	040
20600	040
20605	040
20610	040
64612	0211
64613	0211
64614	0971
64400–64418	0211
64425	0211
64430	0211
64435	0211
64445	0211
64450	0211
64505	0211
64508	0211

• Level II Nerve Injections (to include Moderate Complexity Nerve Blocks and Epidurals):

CPT Code	Reassigned from APC
27096	0210
62270	0210
62272	0210
62273	0212
62310–62319	0212

• Level III Nerve Injections (to include Moderately High Complexity Epidurals, Facet Blocks, and Disk Injections):

CPT Code	Reassigned from APC
62280–62282	0212
62290	([1])
62291	([1])
64420–64421	0211
64470	0211
64472	0211
64475–64476	0211
64479	0211
64480	0211
64483–64484	0211
64510	0211
64520	0211
64530	0211
64630	0211
64640	0211

[1] Currently packaged.

• Level IV Nerve Injections (to include High Complexity Lysis of Adhesions, Neurolytic Procedures, Removal of Implantable Pumps and Stimulators):

CPT Code	Reassigned from APC
62263	0212
64600	0211
64605	0211
64610	0211
64620	0211
64622–64623	0211
64626–64627	0211
64680	0211
62355	0105
62365	0105

• Level V Nerve Injections (to include Highest Complexity Disk and Spinal Endoscopies): CPT code 62287, Aspiration or decompression procedure, percutaneous, of nucleus pulposus of invertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous diskectomy, percutaneous laser diskectomy), reassigned from APC 0220, Level I Nerve Procedures.

The Panel recommended reassignment of CPT code 64614 from APC 0971 to APC 0211.

Concerning the suggested regrouping of interventional pain procedures, the Panel agreed that the recommended division of these procedures by clinical complexity would reflect resource use and was a reasonable approach to take. It was pointed out to the Panel that the costs for CPT codes 62290, Injection procedure for diskography, each level; lumbar, and 62291, Injection procedure for diskography, each level; cervical or thoracic, were packaged into the procedures with which they were billed. Therefore, the Panel concurred with the regrouping of procedures to establish

Levels I, II, III, and IV with the following exceptions:

- The Panel recommended that we not include CPT codes 62290 and 62291 in Level III because they are packaged injections and should not be unpackaged and paid separately.
- The Panel opposed moving CPT codes 62355, Removal of previously implanted intrathecal or epidural catheter, and 62365, Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion, from APC 0105 to Level IV Nerve Injections because they were neither clinically similar nor similar in resource use to the other codes assigned to this APC.
- The Panel opposed the creation of Level V Nerve Tests as it included only one code and recommended that CPT code 62287 remain in APC 220.
- We proposed to accept the Panel's recommendations for these services and we proposed to create new APCs 0203, 0204, 0206, and 0207 to accommodate these changes. We are adopting these proposed changes as final.

APC 0215: Level I Nerve and Muscle Tests

APC 0216: Level II Nerve and Muscle Tests

APC 0217: Level III Nerve and Muscle Tests

We advised the Panel that we had received a comment contending that assignment of CPT code 95863, Needle electromyography, three extremities with or without related paraspinal areas, to APC 0216 created an inappropriate incentive to perform tests on three extremities rather than two or four extremities. The payment of about $144 for APC 0216 is greater than the payment of about $58 for the same tests when performed on one, two, or four extremities. This is because CPT codes 95860, 95861, and 95864, Needle electromyography, one, two, and four extremities with or without related paraspinal areas, respectively, are assigned to APC 0215. We distributed data to the Panel that showed a median cost of about $141 for CPT code 95863, which is more than 3 times that of the median cost of $41 for CPT code 95864. We asked the Panel to consider the reassignment of CPT code 95863 from APC 0216 to APC 0215 and advised the Panel that, based on cost data available at the time of our meeting, this change could potentially reduce the payment for APC 0216. It was also noted that this change could result in a payment increase for APC 0215.

The Panel reviewed the cost data for APCs 0215 and 0216 and noted that the median costs for both CPT codes 95863 and 95864 appeared aberrant. Based on the information presented, the Panel recommended that we move CPT code 95863 from APC 0216 to APC 0215. We proposed to accept the Panel's recommendation with one exception. We proposed to revise these APCs based on the 1999–2000 cost data and the 2 times rule, and CPT code 95863 would be assigned to a reconfigured APC for Level II Nerve and Muscle Tests (APC 0218).

The changes we proposed to APCs 0215, 0216, and 0217 have been adopted as final in this document.

APC 0237: Level III Posterior Segment Eye Procedures

We advised the Panel that procedures assigned to APC 0237 are high volume procedures and rank among the top outpatient procedures billed under Medicare. We have received a number of comments disagreeing with the assignment of CPT code 67027, Implantation of intravitreal drug delivery system (e.g., ganciclovir implant), includes concomitant removal of vitreous, to APC 0237. This procedure was added to the CPT coding system after 1996 and, therefore, was not included in the 1996 data. We advised the Panel that ganciclovir, the drug implanted during this procedure, is paid separately as a transitional pass-through item. Because the drug is paid separately, it should not be included in determining whether the resources associated with the surgical procedure are similar to the resources required to perform the other procedures assigned to APC 0237. We advised the Panel that, of the procedures assigned to APC 0237, we believe that CPT code 67027 is related to codes 65260, 65265, and 67005, all of which involve removal of foreign bodies and vitreous from the eye. To ensure that CPT code 67027 is assigned to the appropriate APC, we asked the Panel to consider creation of a new APC, Level IV Posterior Segment Eye Procedures, for CPT codes 65260, 65265, 67005, and 67027. Based on the APC rates effective January 1, 2001, the suggested change could lower the APC rate for the four procedures by $400.

The Panel reviewed the data and did not believe it was sufficient to support the creation of a new APC for these four procedures. Therefore, the Panel recommended that APC 0237 remain intact and that more recent claims data be analyzed to determine whether CPT code 67027 is similar to the other procedures assigned to APC 0237.

Based on the 1999–2000 claims data, we have determined that the resources used for code 67027 are similar to other procedures in APC 0237. However, we will present APCs 0235, 0236, and 0237 to the Panel at their next meeting to determine whether any further changes should be made. We proposed to make various other changes to these APCs based on the new data and the 2 times rule, which we are incorporating as final in this document.

APC 0251: Level I ENT Procedures

This APC violates the 2 times rule because it consists of a wide variety of minor ENT procedures, many of which are low volume services or codes for nonspecific procedures. In order to correct this problem, we recommended to the Panel that this APC be split by surgical site (for example, nasal and oral). After reviewing cost data, the Panel agreed that the APC should be split but that current data were insufficient to determine how that split should be made. Therefore, the Panel asked that this APC, along with more recent cost data, be placed on the agenda at the next meeting.

We agree that this APC should be reviewed by the Panel at its next meeting. However, our review of the more recent cost data indicates that significant violations of the 2 times rule still exist. In order to correct this problem, but keep the APC as intact as possible, we proposed to move CPT codes 30300, Remove foreign body, intranasal; office type procedure, 40804, Removal of embedded foreign body, vestibule of mouth; simple, and 42809, Removal of foreign body from pharynx, to APC 0340, Minor Ancillary Procedures. This APC consists of procedures such as removal of earwax that require similar resources. Based on the latest 1999–2000 data, we find that the reasons for our proposed revision are still valid, therefore, we have incorporated those changes as final in this rule.

APC 0264: Level II Miscellaneous Radiology Procedures

We asked the Panel to review this APC because it violated the 2 times rule and consisted of a wide variety of unrelated procedures. Specifically, we believe that the costs associated with CPT codes 74740, Hysterosalpingography, radiological supervision and interpretation, and 76102, Radiologic examination, complex motion (e.g., hypercycloidal) body section (e.g., mastoid polytomography), other than with urography; bilateral, were aberrant and that we would significantly underpay these procedures if we moved them into a lower paying APC. We also asked the Panel to determine whether this APC

and APC 0263, Level I Miscellaneous Radiology Procedures, should be reconfigured by body system.

After considerable discussion, the Panel agreed that the procedures in these APCs were not clinically homogeneous; however, it recommended that we leave these APCs intact because the data do not support any more coherent reorganization. The Panel requested that this APC be placed on the agenda for the 2002 meeting.

We stated in the proposed rule that we agreed with the Panel's recommendations with the following revisions. First, BIPA requires us to assign procedures requiring contrast into different APCs from procedures not requiring contrast. This required changes to a number of radiologic APCs including APCs 0263 and 0264. In addition, we proposed to move CPT code 75940, Percutaneous Placement of IVC filter, radiologic supervision and interpretation, to a new APC 0187, Placement/Reposition Miscellaneous Catheters, because its costs were significantly higher than the costs of the procedures remaining in APC 0264.

We are adopting the changes discussed in the proposed rule as final. However, as discussed in a comment and response below in section II.A.3 of this preamble, we are revising the title and status indicator for APC 0187.

APC 0269: Echocardiogram Except Transesophageal

APC 0270: Transesophageal Echocardiogram

We asked the Panel to consider splitting these APCs based on whether or not 2D imaging is employed. After review of the data, the Panel recommended that we leave these APCs intact.

We proposed to leave APC 0270 intact except for the addition of two new codes for transesophageal echocardiography. We also proposed to split APC 0269 into two APCs, APC 0269, Level I Echocardiogram Except Transesophageal and APC 0697, Level II Echocardiogram Except Transesophageal. One APC (0269) would include comprehensive echocardiograms and the other APC (0697) would include limited/follow-up echocardiograms and doppler add-on procedures.

We have included these proposed changes in the APCs set forth in this final rule.

APC 0274: Myelography

We advised the Panel that APC 0274 is clinically homogeneous but that it violates the 2 times rule. Procedures assigned to this APC include radiological supervision and interpretation of diagnostic studies of central nervous system structures (e.g., spinal cord and spinal nerves) performed after injection of contrast material. We shared data with the Panel that showed the median costs for the procedures assigned to this APC ranged from a low of about $109 to a high of about $295. We asked the Panel's recommendation for reconfiguring APC 0274 to comply with the 2 times rule.

We informed the Panel members that we packaged the costs associated with radiologic injection codes into the radiological supervision and interpretation codes with which they were reported. The reason for doing this is that hospitals incur expenses for providing both services and they typically perform both an injection and a supervision and interpretation procedure on the same patient. Therefore, since neither an injection code nor a supervision and interpretation code should be billed alone, it would not be appropriate for us to use single claims data to determine the costs of performing these procedures. However, we are using single claims data in order to accurately determine the costs of performing procedures. Therefore, in order to accurately determine the costs of a complete radiologic procedure, we had to package the costs of the injection component into the cost of the supervision and interpretation component with which it was billed.

The Panel recommended the following:

- Make no changes to APC 0274.
- Review new cost data to determine whether payment would increase for APC 0274.

We proposed to accept the Panel's recommendation. We have made no further changes in this APC.

APC 0279: Level I Diagnostic Angiography and Venography

APC 0280: Level II Diagnostic Angiography and Venography

We presented these codes to the Panel for several reasons. APC 0279 violates the 2 times rule, there are numerous codes in these APCs with no cost data, there are numerous ''add on'' codes in these APCs, and many of these procedures were performed infrequently in the outpatient setting in 1996.

The Panel recommended the following:

- Create a new APC (APC 0287, Complex Venography) with the following CPT codes: 75831, 75840, 75842, 75860, 75870, 75872, and 75880.
- Move CPT codes 75960, 75961, 75964, 75968, 75970, 75978, 75992, and 75995 from APC 0279 to APC 0280.

We proposed to accept the Panel's recommendations. We noted that, as proposed, APC 0279 violated the 2 times rule because of the low cost data for CPT code 75660, Angiography, external carotid, unilateral selective, radiological supervision and interpretation. We believe that, for these procedures, these cost data are aberrant. This code is clinically similar to the other codes in APC 0279 and moving code 75660 to an APC with a lower weight could be an inappropriate APC assignment. Therefore, we stated in the proposed rule that we believe that an exception to the 2 times rule is warranted.

We are adopting the proposed changes as final. We note that APC 0279 continues to violate the 2 times rule due to the median cost of CPT code 75660. However, we continue to believe an exception is warranted.

APC 0300: Level I Radiation Therapy

APC 0302: Level III Radiation Therapy

As discussed in the proposed rule, we presented this APC to the technical advisory Panel because we had received comments that the assignment of CPT code 61793, Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), one or more sessions, to APC 0302 would result in inappropriate payment for this service. Many commenters wrote that stereotactic radiosurgery and intensity modulated radiation therapy (IMRT) required significantly more staff time, treatment time, and resources than other types of radiation therapy. Other commenters disagreed with our decision, effective January 1, 2001, to discontinue recognizing CPT code 61793, and to create two HCPCS level 2 codes, G0173, Stereotactic radiosurgery, complete course of therapy in one session, and G0174, Intensity modulated radiation therapy (IMRT) plan, per session, to report both stereotactic radiosurgery and IMRT.

We reported to the Panel that the APC assignment of these G codes and their payment rate was based on our understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session, while IMRT was performed on an outpatient basis and required several sessions to deliver a complete course of treatment. We also explained to the Panel that it was our understanding that multiple CPT codes were billed for each session of stereotactic radiosurgery and

IMRT. Therefore, we believed that the payment for APC 0302 was only a fraction of the total payment a hospital received for performing stereotactic radiosurgery or IMRT on an outpatient basis.

Radiosurgery equipment manufacturers, physician groups, and patient advocacy groups submitted comments and provided testimony to the APC Panel on these issues. These comments convinced us that we did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services.

We proposed a new coding structure to more accurately reflect the clinical use of these services and the resources required to perform them. In the proposed rule, we stated that there are essentially two services required to deliver stereotactic radiosurgery and IMRT. First, there is ''treatment planning,'' which includes such activities as determining the location of all normal and abnormal tissues, determining the amount of radiation to be delivered to the abnormal tissue, determining the dose tolerances of normal tissues, and determining how to deliver the required dose to abnormal tissue while delivering a dose to adjacent normal tissues within their range of tolerance. We noted that planning activities include the ability to manufacture various treatment devices for protection of normal tissue as well as the ability to ensure that the plan will deliver the intended doses to normal and abnormal tissue by simulating the treatment. Second, there is ''treatment delivery,'' which is the actual delivery of radiation to the patient in accordance with the treatment plan and includes such activities as adjusting the collimator (a device that filters the radiation beams), doing setup and verification images, treating one or more areas, and performing quality control.

We noted that treatment planning for IMRT requires specialized equipment including a duplicate of the actual equipment used to deliver the treatment, the ability to perform a CT scan, various disposable supplies, and involvement of various staff such as the physician, the physicist, the dosimetrist, and the radiation technologist. Treatment delivery requires specialized equipment to deliver the treatment and the involvement of the radiation technologist. The physician and physicist provide general oversight of this process.

Our proposal stated that although there are several types of equipment, produced by several manufacturers, used to accomplish this treatment, it was the consensus of the commenters and the Panel that the most useful way to categorize stereotactic radiosurgery and IMRT is by the source of radiation used for the treatment and not by the type of equipment used. One reason for this is that the clinical indications for stereotactic radiosurgery and IMRT overlap. Therefore, a single disease process can be treated by either modality but the cost of treatment varies by source of radiation used for the treatment. Second, while both stereotactic radiosurgery and IMRT can deliver a complete course of treatment in either one or multiple sessions, the cost of treatment delivery per session is relatively fixed, and is closely related to the source of radiation used for the treatment. On the basis of this understanding we made the following proposal: Appropriate APC assignment and payment were to be made by creating four HCPCS codes to describe these services.

The proposed codes are as follows:

- GXXX1 Multi-source photon stereotactic radiosurgery (Cobalt 60 multi-source converging beams) plan, including dose volume histograms for target and critical structure tolerances, plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, all lesions treated, per course of treatment.
- GXXX2 Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, per lesion.
- G0174 Intensity modulated radiation therapy (IMRT) delivery to one or more treatment areas, multiple couch angles/fields/arcs custom collimated pencil-beams with treatment setup and verification images, complete course of therapy requiring more than one session, per session.
- G0178 Intensity modulated radiation therapy (IMRT) plan, including dose volume histograms for target and critical structure partial tolerances, inverse plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, per course of treatment.

We also proposed that HCPCS codes GXXX1, G0174, and G0178 have status indicators of S, while GXXX2 has a status indicator of T. We believe these are the correct status indicators because G0178 has a ''per session'' designation, while GXXX2 has a ''per lesion'' designation. This was based on our understanding that GXXX1 would not be billed on a ''per lesion'' basis as the planning process would take into account all lesions being treated and it would be extremely difficult to determine resource utilization for planning on a ''per lesion'' basis. Because the costs of performing GXXX1 will vary based on the number of lesions treated, payment would reflect a weighted average.

We based our proposal on our understanding that single-source photon stereotactic radiosurgery (or linear accelerator) planning and delivery are similar to IMRT planning and delivery in terms of clinical use and resource requirements. Therefore, we proposed to require coding for single-source photon stereotactic radiosurgery under HCPCS codes G0174 and G0178.

We also noted that the AMA is establishing codes for IMRT planning and treatment delivery for 2002 and we proposed to retire G0174 and G0178 (with the usual 90-day phase out) and recognize the applicable CPT codes when they are established in January 2002.

Because all activities required to perform stereotactic radiosurgery and IMRT were to be included in the codes described above, we proposed to discontinue the use of any other radiation therapy codes for activities involved with planning and delivery of stereotactic radiosurgery and IMRT for purposes of hospital billing in OPPS. Therefore, we also proposed continuing to not recognize CPT code 61793 for hospital billing purposes.

We believed that our proposal would not only simplify the reporting process for hospitals, but also appropriately recognize the clinical practice and resource requirements for stereotactic radiosurgery and IMRT.

We sought comments on our proposal, including the code titles, descriptors, and coding requirements discussed above. We also requested information regarding appropriate APC assignment and payment rates to inform our decision-making. We specifically asked for information regarding the costs of treatment delivery including any differences between the cost of a complete treatment in single versus multiple sessions.

Finally, we noted that several commenters had requested placement of the stereotactic delivery codes in surgical APCs, therefore, we requested clarification and support for these comments within the context of our coding proposal. Specifically, we were concerned that appropriate payment be made for GXXX2, which has a ''per lesion'' descriptor.

We received numerous comments on our proposal. These comments concerned our proposed coding scheme

and payment amounts as well as the need for separate codes recognizing linear accelerator-based radiosurgery. Many of the comments were part of a write-in campaign asking us to categorize radiosurgery as a surgical procedure and not a radiologic procedure. These letters also asserted that our payment amount for stereotactic radiosurgery should be $15,000. Below, we address each major issue raised by the commenters.

Comment: We received several comments regarding our coding proposal. The commenters indicated the following:

- Our proposed codes are duplicative of currently existing codes.
- We should recognize CPT code 61793 in the APC system.
- Our proposed codes would not allow billing for single session and fractionated linear accelerator-based radiosurgery.
- We incorrectly believe that multisession radiosurgery is similar in resource use to IMRT.
- We should delete our proposed codes for stereotactic radiosurgery planning and recognize CPT code 77295 for this purpose.
- CMS should clarify the other codes that would be billable with our proposed codes.
- Conflicting comments on whether the proposed code for stereotactic radiosurgery delivery should be ''per lesion'' or ''per session'' or ''per course of treatment.''

Commenters were also concerned about our ability to establish APC weights using claims that contained two significant procedures (e.g., stereotactic radiosurgery planning and stereotactic radiosurgery delivery).

Response: We reviewed all these comments very carefully. After completing our review, we have decided to make the following modifications to our proposed coding scheme:

- IMRT—We are not making any changes to our proposal for IMRT coding. We will delete the applicable G codes (G0174 and G0178) and recognize the new CPT codes for IMRT planning (code 77301) and IMRT delivery (code 77418) as established by the AMA.
- GXXX1—Under our proposal, GXXX1 (now G0242) would have been used only for Cobalt-based radiosurgery. After review of the comments, we believe that the planning for Cobalt-based and linear accelerator-based radiosurgery is similar both clinically and in terms of resource consumption. Therefore, at the next coding update, we will change the descriptor for this code to include linear accelerator-based radiosurgery planning. We do not know whether radiosurgery planning is similar clinically and in terms of resource consumption to CPT code 77295 (therapeutic radiology simulation-added field setting; three-dimensional). Use of G0242 will allow us to collect claims data and cost information that will aid us in determining whether G0242 is similar in resource use to 77295. However, we believe that tracking the utilization of G0242 as well as the codes with which it is submitted is very important for future APC reclassification and recalibration purposes, therefore, at this time, we do not intend to discontinue use of this code.
- GXXX2—Most of the comments concerned whether this code (now G0243) should be ''per lesion.'' After extensive review of the comments, we have determined that it is more appropriate for this code to be used ''per session'' or ''per course of treatment.'' We have concluded that the resource consumption for stereotactic treatment delivery varies significantly depending on the size, shape, and depth of the lesion(s) being treated. It is quite possible for the treatment of two superficial, spherical lesions to be less resource intensive than the treatment of a single, large, irregular lesion deep within the brain. Furthermore, the method of treatment and the manner in which the resources are used make a ''per lesion'' description inappropriate. For example, in Cobalt-based treatment, patients are administered ''spheres of dose'' and moved in and out of the machine after each ''sphere of dose.'' The number of ''spheres of dose'' per lesion varies widely so therefore ''per sphere of dose'' might be an alternative description for this service. However, we have concluded that any descriptor other than ''per session'' or ''per course of treatment'' will result in, or create the incentive to bill for, inappropriate payments for this service. Furthermore, it is our understanding that hospitals usually have a single charge for this service and that charge is based on the average resource use for all patients undergoing the procedure whether those patients have one, two, or more lesions treated. Because of the variability of treatment delivery per lesion, hospitals would be overpaid for multi-lesion patients if their charge is based on the average resource use over all patients. Finally, a ''per session'' description is more consistent with a prospective payment system. Because a ''per session'' payment reflects an average that includes all patients, unless a hospital specializes in treatment of multi-lesion patients, the OPPS payment is likely to be appropriate across all patient types. That is, the payment will be slightly higher than costs for single lesion treatments, and slightly lower than costs for multiple lesion treatments, averaging out over all patients.
- Linear accelerator-based radiosurgery—This treatment poses an especially difficult problem because linear accelerator-based radiosurgery can be delivered in a single dose like Cobalt-based treatment, or it can be delivered in fractions, with a maximum of five fractions. We do not have any cost information concerning the resource use of linear accelerator-based treatment delivery, but we do understand that there are two types of linear accelerator-based delivery of radiosurgery: ''gantry-based'' and ''image-directed.'' We do not know if the resource use of these two subtypes of linear accelerator based-radiosurgery is similar. Furthermore, we do not know whether the total resource consumption of fractionated radiosurgery delivered from a linear accelerator is different from the resource consumption of single dose radiosurgery delivered by a linear accelerator.

Therefore, in order to collect data on this procedure, we will designate current code G0173 for reporting single session radiosurgery delivered by a linear accelerator, either gantry-based or image-directed. At the next coding update, we will revise the descriptor for G0173 to reflect this change. Additionally, at the next coding update, we will create a new G code for use by facilities for fractionated radiosurgery delivered by a linear accelerator (either gantry-based or image-directed). The number of fractions will be limited to no more than five. Both G0173 and the new code for fractionated linear accelerator-based radiosurgery will be temporary while we collect cost and utilization data for these services. Once we have collected these data, we will determine whether permanent codes are needed.

In general, we have tried to strike a balance between recognizing clinically dissimilar treatments with individual codes and avoiding the creation of equipment-specific codes for purposes of the OPPS. We believe that the codes established in this final rule reflect this balance.

For multiple procedure claims, we do not believe there is a problem recognizing claims with more than one significant procedure to assist us in determining appropriate APC weights. We have analyzed all the claims in the 1999–2000 data base for CPT code 61793 to determine the codes with which it was billed and in what

frequencies. We have developed coding edits based on this claims analysis and, as discussed below, the payments for stereotactic radiosurgery reflect the median costs for all services that will be included in the payment for stereotactic radiosurgery planning and delivery. We have discussed these coding edits in great detail with the American Society for Therapeutic Radiology and Oncology (ASTRO) and they concur with the edits.

Comment: Many commenters asked us to place stereotactic radiosurgery in a ''surgical'' APC.

Response: We do not understand these comments. We realize that a neurosurgeon is present during stereotactic radiosurgery but, unlike the hospital inpatient PPS, we have no APC designation of ''surgical.'' We have interpreted this comment to mean that commenters do not want stereotactic radiosurgery to be in the same APC as IMRT or fractionated stereotactic radiosurgery. As discussed below, our new assignments of the codes to APCs will effectively create this change.

Comment: We received numerous comments concerning the status indicators we had proposed for the various radiosurgery procedures.

Response: In view of the change in the descriptor for G0243, we will be changing the status indicator for G0243 to ''S.'' This is because there will not be multiple units of this service billed and the costs for providing single dose stereotactic radiosurgery is relatively fixed and it would be inappropriate to give this procedure, as finalized, a ''T'' designation (that is, the multiple procedure reduction is not applicable).

Comment: Many comments addressed the payment rate for stereotactic radiosurgery and IMRT. Suggested amounts for payment of IMRT treatment planning and delivery varied from less than $300 to over $2,000 and suggested amounts for radiosurgery planning and treatment ranged from less than $1,000 to $15,000.

Response: We have no cost data specifically associated with IMRT upon which to base payment for IMRT. Therefore, we used information that provided the basis for IMRT payment under the physician fee schedule and we have established APC assignments that result in payment rates for IMRT planning and treatment delivery similar to payment under the physician fee schedule. We believe this is appropriate because the resource use for these procedures is similar in freestanding facilities and in hospitals. Because we have no claims data on the costs of IMRT, these procedures will be assigned to new technology APCs. As cost data are incorporated in the OPPS claims data base, they will be used to recalibrate the payment for these services and determine their future APC assignment. We would note that payment for IMRT planning includes payment for the following CPT codes: 77300, 77280–77295, 77305–77321. The only CPT codes that may be billed in addition to G0242 (IMRT planning) are the CPT codes 72332–72334 for treatment devices. We plan to incorporate the costs of those codes into IMRT planning when we have collected the cost data. The APC assignment for G0242 is APC 0714, New Technology—IX ($1250–$1500).

In order to determine appropriate payment amounts for both planning and treatment of stereotactic radiosurgery, we did an extensive analysis of our claims data base for code 61793 because that was the code used for stereotactic radiosurgery during 1999–2000. We collected all claims for 61793 and determined which CPT codes were billed with 61793 and the frequency with which each of those codes was billed with 61793. Within the subset of claims including CPT code 61793, we determined the median costs for 61793 and for each CPT code billed with 61793. In analyzing these claims, it was clear that 61793 was generally used to bill for treatment delivery and other codes were used, in combination, to bill for treatment planning. For example, 61793 was billed with 77300 on 57 percent of the claims, with either 77295 or 77290 on 62 percent of the claims, with either 77370 or 77336 on 77 percent of the claims (occasionally both of these codes were on the same claim), and with either 77305, 77315, or 77321 on 59 percent of the claims.

Based on these data, we have determined the total cost for stereotactic radiosurgery as follows: For stereotactic radiosurgery planning, we added the median costs (when billed with 61793) of 77295 (the most typical simulation code billed with 61793), 77300, 77370 (the most common physics consult billed with 61793), and 77315 (the most common dose plan billed with 61793) and will use the sum of these medians as the basis for our APC assignment for 2002. The medians of these codes are: $134.06 for 77300; $146.97 for 77370; $955.88 for 77295; and $206.56 for 77315. The total median cost for these codes is $1,443.47. Effective for services furnished on or after January 1, 2002, we will no longer allow these codes to be billed with stereotactic radiosurgery. No other codes were billed frequently enough with 61793 to justify including their costs in our stereotactic radiosurgery planning code. However, treatment device codes (77332–77334) were billed with 61793 on 42 percent of the claims, so we will allow one of those codes to be billed with each claim for stereotactic radiosurgery. We will consider incorporating their costs into the payment for stereotactic radiosurgery in the future. We note that the median cost of 77334 (the most common treatment device code billed with 61793) was $174.27 when it was billed with 61793.

CPT Code 20660, application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure), was billed with 61793 on only 23 percent of the claims. Because 20660 is required in order to perform stereotactic radiosurgery treatment, we will package the costs associated with 20660 into G0243, the radiosurgery treatment delivery code. We also note that 61793 was billed with an MRI of the brain on 71 percent of the claims. We will allow CTs and MRIs to be billed in addition to stereotactic radiosurgery planning.

For stereotactic radiosurgery delivery, we determined that the median cost of 61793 (using all claims) was $5,734.22 and will use that amount as the basis for our APC assignment for stereotactic radiosurgery for 2002. No other radiotherapy treatment code was billed frequently enough with 61793 to justify incorporation of its cost into our payment (that is, the treatment code most commonly billed with 61793 was 77470 (33 percent of the claims) and the next most common was 77412 (6 percent of the claims)). We will not allow billing of any other radiation treatment delivery codes with stereotactic radiosurgery treatment.

Therefore, we are assigning G0243 to APC 0721, New Technology—XVI ($5,000 to $6,000).

We will pay the same amount for linear accelerator-based stereotactic radiosurgery as for multiple source-based radiosurgery. For fractionated linear accelerator-based radiosurgery, we will divide the payment for single session radiosurgery by five and allow up to five payments. This will make total payment for fractionated linear accelerator based radiosurgery similar to linear accelerator-based single dose radiosurgery while allowing us to collect cost and utilization data for setting payments in 2003. Note that because application of a stereotactic frame is not required for linear accelerator-based radiosurgery, we will not be packaging the costs of code 20660 into the costs for linear accelerator-based radiosurgery.

Linear accelerator-based radiosurgery planning will be coded with the same

code as multiple source-based radiosurgery; therefore, the APC assignment will be the same as well. We note that all of these codes associated with radiosurgery are assigned to new technology APCs as we have no claim data on the procedures. Once we have collected data, the procedures will be assigned to other APCs.

The final APC assignments are as follows:

- 77301 is assigned to APC 0712
- 77418 is assigned to APC 0710
- G0173 is assigned to APC 0721
- G0242 is assigned to APC 0714
- G0243 is assigned to APC 0721.

APC 0311: Radiation Physics Services

APC 0312: Radio Element Application

APC 0313: Brachytherapy

We presented APC 0311 to the Panel because we believed our cost data for CPT codes 77336, Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy; 77370, Special medical radiation physics consultation; and 77399, Unlisted procedure, medical radiation physics, dosimetry, and treatment devices, and special services, were inaccurate. We were concerned that these procedures, particularly code 77370, were not being paid appropriately in APC 0311.

Presenters pointed out that, as with all radiation oncology services, the usual practice is to bill multiple CPT codes on the same date of service. Therefore, single claims were likely to be inaccurate bills and did not represent the true costs of the procedure. For this reason, presenters believed that using single claims to set payment rates for radiation oncology procedures was inappropriate and that we needed to develop a methodology that allowed the use of multiple claims data to set payment rates for these services.

For radiation physics consultation, presenters stated that the staff costs associated with CPT code 77370 were significantly greater than the costs of CPT codes 77336 and 77399. Therefore, they recommended that CPT codes 77336 and 77399 be moved from APC 0311 to APC 0304, Level I Therapeutic Radiation Treatment Preparation, and CPT code 77370 be moved from APC 0311 to APC 0305, Level II Therapeutic Radiation Treatment Preparation. The Panel agreed with this recommendation and we proposed to accept the Panel's recommendation. We also agreed that we should review the use of single claims to set payment rates for radiation oncology services. We plan to present this issue again at the 2002 Panel meeting.

We presented APCs 0312 and 0313 to the Panel because commenters were concerned that the payment rates were too low for the procedures assigned to the APCs and that there were insufficient data to set payment rates for these APCs. The Panel agreed that the issue regarding the use of single claim data affected the payment rates for these services. However, there were insufficient data for the Panel to make any recommendations regarding these APCs. The Panel did request to look at the issue of radiation oncology at its 2002 meeting.

Therefore, we proposed to make no changes to APCs 0312 and 0313 but will address radiation oncology issues at the Panel's 2002 meeting. We note that our updated claims data show very few single claims for procedures in these APCs. However, moving any of these procedures into other radiation oncology APCs would lower their payment rates. We are making no further changes to these APCs.

APC 0371: Allergy Injections

We presented this APC to the Panel because it violates the 2 times rule. The median costs for CPT codes 95115, Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection, and 95117, Professional services for allergen immunotherapy not including provision of allergenic extracts; two or more injections, were lower than the median costs for the other services in this APC.

The Panel agreed that because codes 95115 and 95117 included administration of an injection only, the resource utilization for these services was lower than for the other services. The other services involve preparation of antigen and require more staff time and hospital resources to perform.

In order to create clinical and resource homogeneity, the Panel recommended that we create a new APC for codes 95115 and 95117 and that we leave the other services in APC 0371. We proposed to accept the Panel recommendation and create a new APC 0353, Level II Allergy Injections, and revise the title of APC 0371 to Level I Allergy Injections. These proposed changes are incorporated as final in this rule.

Observation Services

See the discussion on observation services in section II.C.4 of this preamble for the Panel's recommendations and our proposal as well as a discussion of the comments we received.

Inpatient Procedure List

See the discussion of the inpatient procedures list in section II.C.5 of this preamble for the Panel's recommendations and our proposal and a discussion of the comments we received on the list.

3. Other APC Issues

APC 0285: Positron Emission Tomography (PET)

Comment: Commenters expressed concern about the calculation of the payment rate for APC 0285, Positron Emission Tomography (PET), which includes PET for myocardial perfusion imaging. One specific concern is that single service claims are used to calculate relative weights although the applicable procedure codes for these studies are always linked to another diagnostic study and, therefore, they should not appear on single service claims. Second, the commenters are concerned that it is not appropriate to place both single study and multiple study PET procedures in the same APC.

Response: While the PET procedures are linked with a previous diagnostic procedure, the latter need not have been performed on the same day or in the same facility. Upon review of our claims data base, we find that nearly 50 percent of all claims for PET myocardial perfusion imaging studies are single service claims. We believe this to be a sufficient frequency for setting payment rates consistent with the overall methodology for setting rates in the OPPS. With regard to the second concern, after further analysis of claims, we concluded that there is not sufficient variation in the cost among the relevant codes, whether single or multiple studies, to warrant a change in the APC structure.

PET Scans Assigned to APC 0976: New Technology—Level VII ($750–$1000)

In the April 7, 2000 final rule, we assigned PET scans that use 18-flurodeoxyglucose (FDG) to APC 0980, New Technology—Level XII ($2000–$2500) because there were no claims for these procedures in the 1996 data used to establish the APC relative weights for 2000. However, based on the data from over 4,000 claims for services furnished between July 1, 1999 through June 30, 2000, the data base that was used to set the proposed APC weights, we found that the reported median costs for these procedures was closer to $900. Therefore, in the proposed rule, we

assigned the FDG PET scans to APC 0976, New Technology—Level VII ($750–$1000). We received a large number of comments on this proposed change.

Comment: Commenters expressed concern that the proposed APC assignment resulted in a much reduced payment rate for FDG PET scans. Many of these commenters expressed particular concern that the proposed rate of about $850 would not cover the cost of purchasing FDG in addition to the direct and indirect costs of a PET scan. The commenters requested that we review our data and the data they submitted and assign these procedures to a higher level new technology APC.

Response: As we discussed in detail in the April 7, 2002 final rule (65 FR 18476–78), the purpose of assigning a service to a new technology APC is to pay for a new technology based on its expected costs (as evidenced by data collected by us from various external sources) while we collect claims data that would allow assignment of the service to a clinically appropriate APC based on the actual resource use of the service. Our current policy is that a service remains in a new technology APC for 2 to 3 years while we collect the necessary claims data. (See section VI.G of this preamble for a discussion of changes we are making to this policy effective CY 2002.) Because FDG PET scans were assigned to a new technology APC at the implementation of the OPPS in August 2000, they will continue to be assigned to a new technology APC through 2002. However, when we reviewed the claims data in our 1999–2000 data base, there were about 5,000 single claims for these PET scans, with a median cost of about $900. Therefore, we proposed to move these procedures from APC 0980 to APC 0976.

As requested by the commenters and consistent with our policy on pricing services for assignment to new technology APCs, we reviewed the external data provided by the commenters as well as our claims data. These data suggest that our claims cost data may not have accurately captured the entire costs of the procedure, particularly the cost of the FDG. Based on our analysis, we believe that the cost of an FDG PET scan is between $1,200 and $1,800, with a midpoint of $1,500. According to our methodology for pricing new technology services, these services will be reassigned to APC 0978, New Technology—Level IX ($1250–$1500), which results in a payment rate of $1,375.

Cryoablation of the Prostate

Comment: We received several comments concerning our proposal to place CPT code 55873, cryosurgical ablation of the prostate, into APC 0163, Level IV Cystourethroscopy and other Genitourinary Procedures. Commenters believe that we had insufficient cost data to justify moving this code from its current assignment, APC 0980, New Technology—XI ($1750–$2000). They also believe that cryoablation of the prostate is not clinically similar to other procedures in APC 0163. One commenter requested moving code 55873 into either APC 0984, New Technology—XV ($3500–$5000) or 0132, Level III Laparoscopy.

Response: We have reviewed our 1999–2000 cost data for code 55873, and have 4 claims that show a median cost of just over $4,000, which includes the cost of the procedure as well as the associated devices. The devices associated with this procedure are eligible for transitional pass-through payments. After subtracting the estimated cost of the pass-through devices, we believe that the approximate expected cost of this procedure warrants its assignment to APC 0982 New Technology—XIII ($2500–$3000), with a status indicator of ''T.'' The devices associated with this procedure remain eligible for transitional pass-through payments in 2002 in addition to the APC payment amount.

Water-Induced Thermotherapy

Comment: We received a comment from the manufacturer of the equipment used for water-induced thermotherapy (a treatment for benign prostatic hyperplasia), CPT code 53853, that our proposal to assign this procedure in new technology APC 0977, New Technology—VIII ($1000–$1250) did not accurately reflect the costs and resources required to furnish this procedure. The commenter believes that 53853 should be placed in APC 0982, New Technology—XIII ($2500–$3000) with other minimally invasive thermotherapy treatments for benign prostatic hyperplasia.

Response: We disagree with the commenter and are finalizing our proposal. Based on the information provided by the commenters and our own clinical knowledge, we understand that the resources required to deliver water-induced thermotherapy are less than the resources required for the procedures assigned to APC 0982 (CPT codes 53850, transurethral destruction of prostate tissue; by microwave thermotherapy, and 53852, transurethral destruction of prostate tissue; by radiofrequency thermotherapy). Less intraoperative staff time and less equipment resources are required for 53853 than for the other procedures. In addition, unlike codes 53850 and 53852, which require sedation or regional anesthesia, code 53853 requires only local anesthesia. Finally, recovery time is shorter (in part because of the local anesthesia) and requires fewer facility resources. Therefore, we believe code 53853 is appropriately assigned to APC 0977.

Ultrasound Radiologic Guidance Codes

Comment: Several commenters inquired about a change in the proposed rule that resulted in the packaging of certain ultrasound and radiologic guidance codes. The commenters urged us to publish the data and rationale for these changes and recommended that the proposed changes not be made final, pending further review and a fuller discussion of the proposed changes. The commenters recommended separate rather than packaged payment for the guidance codes.

Response: As we explain above in section II.A.2 of this preamble under the discussion for APC 0151, we accepted the APC Panel's recommendation to consider the use of multiple claims data to determine payment rates for endoscopic retrograde cholangio-pancreatography (ERCP). The payment rate that we proposed for ERCP was based on both single claims for ERCP procedures and on claims that included both an ERCP procedure and a radiologic supervision or guidance procedure. That is, rather than making separate payment for the radiologic supervision and guidance furnished in connection with ERCP, we packaged those costs into the proposed rate for APC 0151.

Our experience using multiple procedure claims to price ERCP in accordance with the Panel's recommendation led us to consider other services that could be priced similarly. We believe that the following procedures assigned to APC 0268, Guidance Under Ultrasound, would never be performed alone, but would always be performed in connection with and be considered integral to the performance of another procedure: 76930, 76932, 76934, 76938, 76941, 76942, 76945, 76946, 76948, 76950, 76960, 76965, G0161. Therefore, if a claim listed one of the procedures in APC 0268 in addition to another procedure, we retained that claim in the pool of single-procedure bills used to calculate median costs for services within the various APCs. Costs

associated with the codes in APC 0268 were therefore packaged into the APCs of procedures with which they were billed between July 1, 1999 through June 30, 2000.

We continue to believe that the most appropriate way to pay for ultrasound guidance is to package its costs as part of the cost of performing the procedure for which the guidance is needed. Therefore, in the proposed rule, we assigned status indicator ''N'' to still active codes that had previously been in APC 0268. We applied the same principle to several radiologic guidance codes (76393, 19290, 19291, and 19295). We assigned status indicator ''N'' to these codes because they represent services that are always furnished in connection with another procedure. That is, they are integral to performing another procedure and would never be performed alone, as a single service. Therefore, costs associated with such radiologic guidance codes are more appropriately packaged than paid for separately.

It is crucial that hospitals bill charges for codes with status indicator ''N'' to ensure that costs for packaged services are appropriately captured in the APCs with which they are associated. For the 2003 OPPS update, we will consider proposing to package additional guidance services with whichever procedures they are billed, including the following:

76095, Stereotactic localization guidance for breast biopsy or needle placement.

76355, Computerized tomography guidance for stereotactic localization.

76360, Computerized tomography guidance for needle placement.

We will report to the Panel on our progress in treating bills with certain packaged services as single procedure claims. We will also include on the agenda of the next Panel meeting a follow-up discussion to review the services that we have packaged thus far and to consider other codes that would also be more appropriately paid as packaged rather than separate services. To identify all the procedures with which the ultrasound and radiologic guidance services are packaged would require a review of the raw outpatient claims that make up the 1999–2000 data that we are using to recalibrate the 2002 APC weights because we have previously packaged the guidance costs with whatever procedure they are billed in preparing the claims data base used for recalibration.

Breast Biopsy

Comment: A few commenters, including the manufacturer of a minimally invasive breast biopsy system, expressed concern that the higher APC relative weight for surgical breast biopsy procedures would discourage Medicare beneficiary access to less invasive procedures. The commenters were also concerned that the proposed payment for less invasive breast biopsy procedures was inadequate.

Response: As we discuss below in section II.D. of this preamble, the APC weights reflect hospital median costs (as determined from the charges reflected on claims submitted by hospitals) for a given procedure relative to the costs for other procedures. We expect that the costs for an open surgical procedure will be higher than those for less invasive procedures because open surgery is more resource intensive, especially in terms of recovery time, anesthesia, and nursing care. We do not agree that the higher relative weight for open surgical biopsy will serve as an incentive to perform this procedure rather than the less costly, less invasive options. The payment rate for the less invasive options are based on the costs of those procedures as reported by hospitals. We note that the payment rate for the breast biopsy procedure assigned to APC 0974, New Technology—Level V ($300–$500) (CPT code 19103, Percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance) is higher in this final rule relative to the proposed rule (see the discussion in section II.D. of this preamble, below).

Comment: Several commenters questioned why the proposed rule indicated that CPT code 76095, Stereotactic localization guidance for breast biopsy, would be moved from APC 0264, Level II Miscellaneous Radiology Procedures, with a status indicator of ''X'' (ancillary service) to APC 0187, Placement/Repositioning Miscellaneous Catheters, with a status indicator of ''T'' (significant procedure, multiple procedure reduction applies). The commenters were concerned that the ''T'' status indicator would result in a lower payment for the procedure when it is billed with other procedures.

Response: We agree with commenters that the title for APC 0187 in the proposed rule is misleading given the procedures that are included within the APC. Therefore, in the final rule, we are changing the name of APC 0187 to ''Miscellaneous Placement/Repositioning''. We are also changing the status indicator for APC 0187 from ''T'' to ''X''. We created APC 0187 to pay more appropriately for certain guidance codes, including code 76095.

Status Indicators

Comment: A commenter asserted that some hospitals believe that procedure codes designated with status indicators of ''S,'' ''T,'' ''V,'' and ''X'' mean that the procedure must be performed in the outpatient setting.

Response: This is not the case. These status indicators were developed to assist us with our pricing policy in OPPS, not to dictate where the procedures could be performed. Although a status indicator of ''C'' means that the procedure will not be paid if performed in the outpatient setting, the status indicators paid under the OPPS do not dictate where that service or procedure is covered. We pay for any covered service or procedure performed in the inpatient setting as an inpatient service as long as the patient's condition merits admission to the hospital as an inpatient.

B. Additional APC Changes Resulting from BIPA Provisions

1. Coverage of Glaucoma Screening

Section 102 of the BIPA amended section 1861(s)(2) of the Act to provide payment for glaucoma screening for eligible Medicare beneficiaries, specifically, those with diabetes mellitus or a family history of glaucoma, and certain other individuals found to be at high risk for glaucoma as specified by our rulemaking. The implementation of this provision is discussed in detail in a separate final rule concerning the revisions in the physician fee schedule payment policy for CY 2002, published in the **Federal Register** on November 1, 2001 (66 FR 55272).

In order to implement section 102 of BIPA, we have established two new HCPCS codes for glaucoma screening:

- G0117—Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist.
- G0118—Glaucoma screening for high risk patients furnished under the direct supervision of an optometrist or ophthalmologist.

We proposed to assign the glaucoma screening codes to APC 0230, Level I Eye Tests. We further proposed to instruct our fiscal intermediaries to make payment for glaucoma screening only if it is the sole ophthalmologic service for which the hospital submits a bill for a visit. That is, the services included in glaucoma screening (a dilated eye examination with an intraocular pressure measurement and direct opthalmoscopy or slit-lamp biomicroscopy) would generally be performed during the delivery of another opthalmologic service that is furnished on the same day. If the

beneficiary receives only a screening service, however, we would pay for it under APC 0230.

2. APCs for Contrast Enhanced Diagnostic Procedures

Section 430 of the BIPA amended section 1833(t)(2) of the Act to require the Secretary to create additional APC groups to classify procedures that utilize contrast agents separately from those that do not, effective for items and services furnished on or after July 1, 2001. On June 1, 2001, we issued a Program Memorandum, Transmittal A–01–73, in which we made numerous coding and grouping changes to implement this provision. (This transmittal can be found at *www.hcfa.gov/pubforms/transmit/AO173.pdf*) We removed the radiological procedures whose descriptors included either ''without contrast material'' or ''without contrast material followed by contrast material'' from APC groups 0282, Level I, Computerized Axial Tomography; APC 0283, Level II, Computerized Axial Tomography; and APC 0284, Magnetic Resonance Imaging. As a result, APCs 0283 and 0284 now include only imaging procedures that are performed with contrast materials. Additionally, reconfigured APC 0282 no longer includes radiological procedures that use contrast agents.

Effective for items or services furnished on or after July 1, 2001, we created six new APC groups for the procedures removed from APCs 0282, 0283, and 0284, as shown below. (Effective October 1, 2001, we eliminated APC 0338. Refer to Transmittal A–01–73 for a detailed description of this change.) For services furnished on or after July 1, 2001 and before January 1, 2002, the payment rates for the new imaging APCs are the same as those associated with the APCs from which the procedures were moved. For the proposed rule, we calculated separate weights for the new APCs based on the data available at the time for recalibration. In this final rule, we are establishing separate weights for the new APCs based on the final data used to recalibrate the weights for 2002.

TABLE 1.—APC GROUPS RECONFIGURED TO SEPARATE IMAGING PROCEDURES THAT USE CONTRAST MATERIAL FROM PROCEDURES THAT DO NOT USE CONTRAST MATERIAL

APC	SI	APC title
0282	S	Miscellaneous Computerized Axial Tomography.
0283	S	Computerized Axial Tomography with Contrast.
0284	S	Magnetic Resonance Imaging and Angiography with Contrast.
0332	S	Computerized Axial Tomography w/o Contrast.
0333	S	CT Angio and Computerized Axial Tomography w/o Contrast followed by with Contrast.
0335	S	Magnetic Resonance Imaging, Temporomandibular Joint.
0336	S	Magnetic Resonance Angiography and Imaging without Contrast.
0337	S	Magnetic Resonance Imaging and Angiography w/o Contrast followed by with Contrast.

The HCPCS codes that are reassigned to the new imaging APCs in this final rule are as follows:

APC	HCPCS	SI	Short descriptor
0282	76370	S	CAT scan for therapy guide.
	76375	S	3d/holograph reconstr add-on.
	76380	S	CAT scan for follow-up study.
	G0131	S	Ct scan, bone density study.
	G0132	S	Ct scan, bone density study.
0283	70460	S	Ct head/brain w/dye.
	70481	S	Ct orbit/ear/fossa w/dye.
	70487	S	Ct maxillofacial w/dye.
	70491	S	Ct soft tissue neck w/dye.
	71260	S	Ct thorax w/dye.
	72126	S	Ct neck spine w/dye.
	72129	S	Ct chest spine w/dye.
	72132	S	Ct lumbar spine w/dye.
	72193	S	Ct pelvis w/dye.
	73201	S	Ct upper extremity w/dye.
	73701	S	Ct lower extremity w/dye.
	74160	S	Ct abdomen w/dye.
	76355	S	CAT scan for localization
	76360	S	CAT scan for needle biopsy.
0284	70542	S	MRI orbit/face/neck w/dye.
	70545	S	Mr angiography head w/dye.
	70548	S	Mr angiography neck w/dye.
	70552	S	MRI brain w/dye.
	71551	S	MRI chest w/dye.
	72142	S	MRI neck spine w/dye.
	72147	S	MRI chest spine w/dye.
	72149	S	MRI lumbar spine w/dye.
	72196	S	MRI pelvis w/dye.
	73219	S	MRI upper extremity w/dye.
	73222	S	MRI joint upr extrem w/dye.
	73719	S	MRI lower extremity w/dye.
	73722	S	MRI joint of lwr extr w/dye.

APC	HCPCS	SI	Short descriptor
	74182	S	MRI abdomen w/dye.
	75553	S	Heart MRI for morph w/dye.
	C8900	S	MRA w/cont, abd.
	C8903	S	MRI w/cont, breast,uni.
	C8906	S	MRI w/cont, breast, bi.
	C8909	S	MRA w/cont, chest.
	C8912	S	MRA w/cont, lwr ext.
0332	70450	S	CAT scan of head or brain.
	70480	S	Ct orbit/ear/fossa w/o dye.
	70486	S	Ct maxillofacial w/o dye.
	70490	S	Ct soft tissue neck w/o dye.
	71250	S	Ct thorax w/o dye.
	72125	S	Ct neck spine w/o dye.
	72128	S	Ct chest spine w/o dye.
	72131	S	Ct lumbar spine w/o dye.
	72192	S	Ct pelvis w/o dye.
	73200	S	Ct upper extremity w/o dye.
	73700	S	Ct lower extremity w/o dye.
	74150	S	Ct abdomen w/o dye.
0333	70470	S	Ct head/brain w/o&w dye.
	70482	S	Ct orbit/ear/fossa w/o&w dye.
	70488	S	Ct maxillofacial w/o&w dye.
	70492	S	Ct sft tsue nck w/o & w/dye.
	70496	S	Ct angiography, head.
	70498	S	Ct angiography, neck.
	71270	S	Ct thorax w/o&w dye.
	71275	S	Ct angiography, chest.
	72127	S	Ct neck spine w/o&w dye.
	72130	S	Ct chest spine w/o&w dye.
	72133	S	Ct lumbar spine w/o&w dye.
	72191	S	Ct angiograph pelv w/o&w dye.
	72194	S	Ct pelvis w/o&w dye.
	73202	S	Ct uppr extremity w/o&w dye.
	73206	S	Ct angio upr extrm w/o&w dye.
	73702	S	Ct lwr extremity w/o&w dye.
	73706	S	Ct angio lwr extr w/o&w dye.
	74170	S	Ct abdomen w/o&w dye.
	74175	S	Ct angio abdom w/o&w dye.
	75635	S	Ct angio abdominal arteries.
0335	70336	S	Magnetic image, jaw joint.
	75554	S	Cardiac mri/function.
	75555	S	Cardiac mri/limited study.
	76390	S	Mr spectroscopy.
	76400	S	Magnetic image, bone marrow.
0336	70540	S	MRI orbit/face/neck w/o dye.
	70544	S	Mr angiography head w/o dye.
	70547	S	Mr angiography neck w/o dye.
	70551	S	MRI brain w/o dye.
	71550	S	MRI chest w/o dye.
	72141	S	MRI neck spine w/o dye.
	72146	S	MRI chest spine w/o dye.
	72148	S	MRI lumbar spine w/o dye.
	72195	S	MRI pelvis w/o dye.
	73218	S	MRI upper extremity w/o dye.
	73221	S	MRI joint upr extrem w/o dye.
	73718	S	MRI lower extremity w/o dye.
	73721	S	MRI joint of lwr extre w/o d.
	74181	S	MRI abdomen w/o dye.
	75552	S	Heart MRI for morph w/o dye.
	C8901	S	MRA w/o cont, abd.
	C8904	S	MRI w/o cont, breast, uni.
	C8910	S	MRA w/o cont, chest.
	C8913	S	MRA w/o cont, lwr ext.
0337	70543	S	MRI orbt/fac/nck w/o&w dye.
	70546	S	Mr angiograph head w/o&w dye.
	70549	S	Mr angiograph neck w/o&w dye.
	70553	S	MRI brain w/o&w dye.
	71552	S	MRI chest w/o&w dye.
	72156	S	MRI neck spine w/o&w dye.
	72157	S	MRI chest spine w/o&w dye.
	72158	S	MRI lumbar spine w/o&w dye.
	72197	S	MRI pelvis w/o&w dye.
	73220	S	MRI uppr extremity w/o&w dye.
	73223	S	MRI joint upr extr w/o&w dye.

APC	HCPCS	SI	Short descriptor
	73720	S	MRI lwr extremity w/o&w dye.
	73723	S	MRI joint lwr extr w/o&w dye.
	74183	S	MRI abdomen w/o&w dye.
	C8902	S	MRA w/o fol w/cont, abd.
	C8905	S	MRI w/o fol w/cont, brst, uni.
	C8908	S	MRI w/o fol w/cont, breast, bi.
	C8911	S	MRA w/o fol w/cont, chest.
	C8914	S	MRA w/o fol w/cont, lwr ext.

Refer to Addendum A or Addendum B of this final rule for the updated weights, payment rates, national unadjusted copayment, and minimum unadjusted copayment for all of the procedures listed above.

3. Coding and Payment for Mammography Services

a. Screening Mammography. Screening mammography means a radiologic procedure provided to a woman without signs or symptoms of breast disease for the purpose of early detection of breast cancer. Under Medicare, screening mammography services can be billed in three ways: (1) For the physician's interpretation of the results of the screening mammogram (that is, the professional component of mammography services); (2) for all services other than the physician's interpretation (that is, the technical component); or (3) for both the professional and technical components (global billing), although global billing is not permitted for services furnished in the hospital outpatient setting.

Section 4163 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) added section 1834(c) of the Act to provide for Part B coverage of screening mammography performed on or after January 1, 1991. Section 1834(c) of the Act governing those screenings did not include screening mammography under the physician fee schedule; it provided for payment under a separate statutory methodology. Payment for screening mammography services furnished in the hospital outpatient setting before January 1, 2002 is subject to the payment method set by the statute at section 1834(c) of the Act. When Medicare implemented the OPPS for services furnished beginning August 1, 2000, payment for screening mammography services continued to be based on the payment method set by the statute at section 1834(c) (the lower of hospital charges or the national payment limitation) of the Act and was not made under the OPPS.

Section 104 of BIPA amended section 1848(j)(3) of the Act to include screening mammography as a physician service. As a result of this amendment, the payment limit that is currently the basis for payment is replaced beginning January 1, 2002 by payment under the Medicare physician fee schedule. Payments for all services under the physician fee schedule are resource-based and have geographic adjustments that reflect cost differences among areas. A discussion of how payment for screening mammography services is determined under the physician fee schedule can be found in the final rule, ''Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002,'' published in the November 1, 2001 **Federal Register** (66 FR 55246). Beginning January 1, 2002, Medicare payment for screening mammography services furnished in a hospital outpatient setting is no longer the lower of hospital charges or the national payment limitation; however, payment will continue to be excluded from the OPPS. For screening mammography furnished in the outpatient setting, Medicare will pay hospitals the technical component amount established under the Medicare physician fee schedule.

Comment: A few commenters questioned why we had not established an APC or a payment rate for screening mammography in the proposed rule. One commenter expressed grave concern that our failure to include an APC for screening mammography in the proposed rule meant that Medicare beneficiaries would not be able to receive screening mammography services in the hospital outpatient setting. These commenters urged that we establish an APC for screening mammography services and that the payment rate be consistent with the cost of taking a screening mammogram in the hospital outpatient setting rather than the payment rate proposed for diagnostic mammograms in APC 0271, Mammography. One commenter, citing a survey conducted by a professional society, reported the average cost of doing a screening mammogram in a hospital to be about $97. Several commenters supported the physician fee schedule payment rate for screening mammography services as a more reasonable recognition of associated costs than the payment rate proposed for diagnostic mammography under APC 0271.

Response: The fact that we have not assigned the HCPCS codes for screening mammography services to an APC does not mean that Medicare does not pay hospitals for these services when they are furnished in the outpatient setting. Rather, as we explain in the April 7, 2000 final rule, we excluded screening mammography services from payment under the OPPS because they were already subject to an existing fee schedule or other prospectively determined payment rate (65 FR 18442). When the OPPS was implemented on August 1, 2000, screening mammography services were assigned payment status indicator ''A'' to specify that payment would be the ''lower of charge or national rate,'' consistent with section 1834(c)(3) of the Act (65 FR 18445).

As a result of section 104 of BIPA, which amended section 1848(j)(3) of the Act to define screening mammography as a physician service, Medicare payment for screening mammography services furnished on or after January 1, 2002 is no longer subject to the payment methodology established under section 1834(c) of the Act. Therefore, payment for both the professional and technical components of screening mammography services furnished on or after January 1, 2002 is made under the physician fee schedule. This means that, effective for services furnished on or after January 1, 2002, the payment amount to hospitals for screening mammography services furnished in the outpatient setting will be based on the amount established for the technical component of screening mammography under the physician fee schedule.

Hospitals are to use the following codes to bill for screening mammography services effective January 1, 2002:

- CPT code 76092, Screening mammography, bilateral (two view film study of each breast)

• HCPCS code G0202, Screening mammography, direct digital image, bilateral, all views

• CPT code 76085, Computer-aided detection add-on code for screening mammography (can only be billed with CPT code 76092)

We further discuss in section II.B.3.c, below, coding and payment for screening and diagnostic mammograms that use advanced new technologies.

Payment for screening mammography services furnished in a hospital outpatient department beginning January 1, 2002 is equal to 80 percent of the lower of the hospital's actual charge or the locality specific technical component payment amount under the physician fee schedule. Coinsurance equals 20 percent of the lower of the actual charge or the physician fee schedule amount. The Medicare Part B deductible does not apply to screening mammography. The November 1 physician fee schedule final rule lists the relative value units for screening mammography services and the physician fee schedule conversion factor for CY 2002 (66 FR 55334). In addition to the technical component payment made to the hospital, physicians are paid an additional amount for professional services furnished in connection with these procedures.

In this final rule, we are changing the descriptor of payment status indicator ''A'' for the screening mammography codes to ''Physician Fee Schedule'' to conform with the BIPA change.

b. Diagnostic Mammography. Medicare covers a radiological mammogram as a diagnostic test under the following conditions:

• A patient has distinct signs and symptoms for which a mammogram is indicated;

• A patient has a history of breast cancer; or

• A patient is asymptomatic, but on the basis of the patient's history and other factors the physician considers significant, the physician's judgment is that a mammogram is appropriate.

Payment for a diagnostic mammogram furnished in a hospital outpatient setting is made under the OPPS. The following codes are used to report diagnostic mammography: CPT code 76090, Mammography; unilateral, and CPT code 76091, Mammography, bilateral are used to report a diagnostic mammogram. These two codes are assigned to APC 0271, Mammography, and we proposed no changes to the assignment of these codes in the proposed rule. (We discuss in section III.B.3.c, below, coding changes for the CY 2002 related to new technology mammography.)

In the proposed rule, the relative weight for APC 0271 was equal to 0.64. We recalibrated all the APC relative weights, including that for APC 0271, using claims data for services furnished beginning July 1, 1999 through June 30, 2000 in accordance with the process explained in the proposed rule (66 FR 44695).

Comment: We received numerous comments, many of which were the product of a ''write-in'' campaign, regarding the relative weight and payment rate proposed for APC 0271. The commenters asserted that the current payment rate for APC 0271 is inadequate to support the provision of mammography services in the hospital outpatient setting, and they expressed disbelief that the proposed payment rate for 2002 is lower than the current rate. Commenters expressed grave concern that the proposed payment rate for diagnostic mammography would have a generally negative impact on beneficiary access to mammography services. Many commenters cited a practice cost survey conducted by the American College of Radiology that indicated the average cost for performing a screening mammogram in a hospital outpatient setting to be $97. The commenters argued that diagnostic mammography is more complex technically and more resource intensive, requiring more than double the clinical labor, supply, and equipment inputs than those required for screening mammography. One commenter stated that the technical cost of providing screening mammography in the hospital setting is nearly twice the cost of providing the same service in a physician office setting.

Other commenters recommended that payment for all mammography services furnished in the outpatient setting, both screening and diagnostic, be paid under the physician fee schedule to eliminate the significant payment disparity that will result if the proposed OPPS rates for diagnostic mammography are implemented in 2002. Several commenters complained that we provided no rationale or data to show how the proposed payment rate for APC 0271 was calculated nor did we explain why the proposed payment for these services is lower than the current payment. Commenters urged that we recalculate the payment rate for APC 0271 to represent a payment rate that is reflective of the resources used to perform the procedure.

Response: We calculated the relative weight for APC 0271 in the April 7, 2000 final rule in accordance with the process we described in that rule (65 FR 18482), using, as required by the statute, claims from 1996 and data from the most recent available hospital cost reports. Because we did not recalibrate the relative weights for any APC groups in the November 13, 2000 final rule, the relative weight (0.70) for APC 0271 as well as the relative weights for the other APC groups have not changed since August 1, 2000.

Using 1999–2000 claims data, we recalibrated all the APC weights in the proposed rule in accordance with the process that we explained in that rule (66 FR 44695). The relative weight for every APC group changed for two reasons: the use of more recent claims data, and the statutory requirements for budget neutrality. Section 1833(t)(9)(B) of the Act requires that estimated spending for services covered under the OPPS be neither greater nor less than it would have been had the recalibration and reclassification changes not been made. Because of this, the weights and, therefore, the payment rates for a specific service may increase or decrease depending on the change in charges hospitals report for that service relative to the change in charges hospitals report for other outpatient services. The decrease in the relative weight for diagnostic mammography proposed for 2002 can be attributed to a decrease in the relative level of charges for diagnostic mammography that hospitals reported for services furnished from July 1, 1999 through June 30, 2000 compared to the relative level of charges hospitals reported for all other outpatient services furnished during the same period. However, that weight does reflect the hospital resources used to perform mammograms. We note that the weight for APC 0271 in both the proposed and final rules is calculated from the median cost of almost 900,000 single-procedure claims.

The weight for APC 0271 in this final rule is 0.60. This weight was recalibrated, like all of the APC weights in this final rule, in accordance with the methodology described in section II.D. of this preamble. We note that the weight for APC 0271, like the weights for all of the nondevice-related APCs, has decreased from the proposed weight. This decrease is the result of our incorporating a portion of the cost of pass-through devices into the base costs of the APCs with which the devices are associated. As we explained in the final rule published on November 2, 2001, the additional pass-through device costs that were incorporated into the base APC costs are not evenly distributed among the APCs, but rather are concentrated in a relatively small

number of APCs that include the procedures that use pass-through devices (66 FR 55862). Whereas the weights of these APCs increased as a result of the added device costs, in general, the weights for APCs that do not include device costs, such as APC 0271, decreased by approximately 8 percent. For a more detailed discussion of how the incorporation of device costs into the base APCs affects the relative weights, see sections II.D. and VII, below.

Unlike screening mammography, the statute makes no specific designation for the technical component of diagnostic mammography services furnished in the hospital outpatient setting to be defined as a physicians' service. Therefore, we believe that the payment for diagnostic mammography should be included in the OPPS.

Comment: Several commenters expressed concern that the reduced payment rate for diagnostic mammography would have an especially onerous and negative impact on small, low volume hospitals, most of which are located in rural areas. The commenters noted that although these small rural hospitals are generally the sole providers of mammography and radiology services to the surrounding communities, volume in these hospitals is nonetheless too low to offset the fixed costs incurred for certified staff and equipment.

Response: In order to limit potential reductions in payment to hospitals under the OPPS, section 1833(t)(7) of the Act requires us to provide transitional payment adjustments for hospitals whose OPPS payments are less than our estimate of the hospital's pre-BBA payments. Section 1833(t)(7)(D)(i) of the Act includes a special ''hold harmless'' provision, which applies to hospital outpatient services furnished before 2004 by hospitals that are located in a rural area and that have no more than 100 beds. Under section 1833(t)(7)(D)(i) of the Act, small rural hospitals will be paid a predetermined pre-BBA amount for services covered under the OPPS if payment under the OPPS would be less than the pre-BBA amount. This hold harmless provision establishes a payment floor until January 1, 2004 for small rural hospitals. These provisions should provide some measure of protection to small hospitals in rural areas to the extent that the reduced payment for diagnostic mammography services results in overall payment reductions.

c. Coding and Payment for New Technology Mammography Services. Section 104(d) of BIPA prescribes a payment methodology for both diagnostic and screening mammography furnished during the period April 1, 2001 through December 31, 2001 that use a new technology, as defined in section 104(d)(3) of BIPA. Section 104(d)(2) of BIPA directs the Secretary to determine, for mammography performed after 2001, whether the assignment of a new HCPCS code is appropriate for mammography that uses a new technology. The following codes have been established to identify the new technology mammography services and will be used effective January 1, 2002:

- *HCPCS code G0202,* Screening mammography producing direct digital image, bilateral, all views.
- *CPT code 76085,* Digitization of film radiographic images with computer analysis for lesion detection and further physician review for interpretation, screening mammography. (This code can only be billed with CPT code 76092, Screening mammography, bilateral.)
- *HCPCS code G0204,* Diagnostic mammography, direct digital image, bilateral, all views.
- *HCPCS code G0206,* Diagnostic mammography, direct digital image, unilateral, all views.
- *HCPCS code G0236,* Digitization of film radiographic images with computer analysis for lesion detection and further physician review for interpretation, diagnostic mammography. (This code can only be billed with code CPT code 76090, Diagnostic mammography, unilateral, or CPT code 76091, Diagnostic mammography, bilateral.)

In the proposed rule, we assigned computer-aided detection (CAD) and full field digital mammography (FFDM) services used for diagnostic mammography to APC 0271. We proposed to assign payment status indicator ''A,'' designating that payment would be ''lower of charges or national rate,'' to the CAD and FFDM codes for screening mammography. Numerous commenters addressed our proposed payment for CAD and FFDM new technology mammography services. Their comments are summarized below.

Comment: One commenter recommended that CAD used in conjunction with film screening mammography be assigned to a new technology APC under the OPPS rather than being paid under the physician fee schedule. The commenter argued that although section 104(a) of BIPA provided for payment for screening mammography under the physician fee schedule, payment for a new technology such as CAD is provided under a separate BIPA provision, section 104(d)(3), and therefore is not linked to the physician fee schedule.

Response: We do not agree with the commenter's recommendation that CPT code 76085 for CAD used with screening mammography be assigned for payment to a new technology APC under the OPPS. Because CPT code 76085 is an add-on code that can be paid only when it is billed with CPT code 76092 for screening mammography, we believe it is more appropriate to pay for both CPT codes 76085 and 76092 under the physician fee schedule than to pay for them separately under two different payment systems.

Comment: Most commenters recommended assignment of CAD and FFDM services used with diagnostic mammography to a new technology APC on the grounds that no existing APC would be appropriate both clinically and in terms of payment for these services. Commenters were unanimous in opposing assignment of the CAD and FFDM services used for diagnostic mammography to APC 0271. Several commenters were concerned that payment for these services under the physician fee schedule was so much higher than that proposed under the OPPS.

Response: We agree that the new technology procedures associated with diagnostic mammography should be assigned to a new technology APC until we have collected cost data to make a more clinically and resource use appropriate APC assignment. Therefore, effective for services furnished on or after January 1, 2002, HCPCS codes G0204 and G0206 will be assigned to APC 0971 and HCPCS code G0236 will be assigned to APC 0970.

The difference in payment amounts for the new technology mammography services between the physician fee schedule and the OPPS is attributable to differences in the payment methodology required under the statute.

Final Action: See section II.B.3.a. for the codes used to bill for new technology screening mammography services. The following codes and APC groups are effective for new technology services used for diagnostic mammography beginning January 1, 2002:

HCPCS codes G0205 and G0207 are deleted.

Use HCPCS codes G0204 and G0206 for full field digital diagnostic mammography services; assigned to APC 0707.

Use HCPCS code G0236 for computer-assisted detection with CPT code 76090 and CPT code 76091 for diagnostic mammography; assigned to APC 0706.

C. Other Changes Affecting the APCs

1. Changes in Revenue Code Packaging

In the April 7, 2000 final rule, we described how, in calculating the per procedure and per visit costs to determine the median cost of an APC (and therefore its relative weight), we used the charges billed using the revenue codes that contained items that were integral to performing the procedure or visit (65 FR 18483). The complete list of the revenue centers by type of APC group was printed in the April 7, 2000 rule (65 FR 18484).

In the November 13, 2000 interim final rule, we made some changes to the list of revenue codes to reflect the charges associated with implantable devices (65 FR 67806 and 67825). We were later able to incorporate revenue codes 274 (prosthetic/orthotic devices), 275 (pacemaker), and 278 (other implants) in our database, and effective January 1, 2001, we updated the APC payment rates to reflect inclusion of this information.

As discussed in the proposed rule, we have continued to review and revise the list of revenue codes to be included in the database and we proposed several changes to the list of revenue codes that are packaged with the costs used to calculate the proposed APC rates. Some of these changes reflect the addition of revenue codes and others are a further refinement of our methodology. The following are the specific changes we proposed:

- Package additional revenue centers that may be used to bill for implantable devices (including durable medical equipment (DME) and brachytherapy seeds) with surgical procedures. These additional centers are revenue codes 280 (oncology), 289 (other oncology), 290 (DME), and 624 (investigational devices).
- Package revenue codes 280, 289, and 624 with other diagnostic and radiology services.
- Package the revenue codes for medical social services, 560 (medical social services) and 569 (other medical social services). These services are not paid separately in the hospital outpatient setting but often constitute discharge-planning services if provided with an outpatient service.
- Package revenue code 637 (self-administered drug (insulin administered in an emergency diabetic coma)) with medical visits. Although this is a self-administrable drug, it is covered when administered as described.
- Remove revenue code 723 (circumcision) from the list of packaged revenue codes because circumcision is a payable procedure under OPPS and should not be packaged.
- Package revenue code 942 (education/training) with medical visits and the category of ''All Other APC Groups.'' Patient training and education are generally not paid as a separate service under Medicare, but may be included as part of an otherwise payable service such as a medical visit. We believe that training and education services generally occur as part of a medical visit or psychiatric service.
- Remove the revenue codes in the range of 890 through 899 (donor bank), as these are no longer valid revenue codes.

Comment: One commenter disagreed with our proposal to package revenue code 942 (education/training). The commenter stated that such a policy would be inappropriate because revenue code 942 is the proper revenue code to use when billing diabetes training with HCPCS codes G0108 and G0109. If CMS does package that revenue code, the commenter wanted to know what revenue code should be billed for diabetes education.

Response: Although under OPPS we will package charges for education and training when billed with revenue code 942, training and education associated with diabetes management, identified by HCPCS codes G0108 and G0109, is not paid under the OPPS and, therefore, is not a packaged service. The list of packaged revenue codes contained in the proposed rule represents revenue codes that are packaged when they appear on a bill with an OPPS service and are not billed with a HCPCS code for a service, like diabetes education, which is paid by Medicare but paid outside of the OPPS.

Comment: One commenter questioned our proposal to package additional revenue centers that may be used to bill for implantable devices (including brachytherapy seeds) with surgical procedures. The commenter asked for details on how such packaging would be accomplished and specifically how we would account for the varying number of costly brachytherapy seeds used in each procedure.

Response: In determining the median cost of a procedure or service, we take into account the costs associated with any packaged revenue center that appears on a bill as well as the cost associated with the specific line item that reflects the HCPCS code for the procedure or service. Thus, when a hospital bills a charge for brachytherapy seeds using one of the revenue codes that are identified as a packaged revenue code, we convert that charge to a cost by multiplying the billed charge by the hospital-specific cost-to-charge ratio for the related cost center. The cost of the brachytherapy seeds is then added to all other costs on the bill that are attributable to the procedure to arrive at the cost of the bill. Under this methodology, the varying numbers of brachytherapy seeds used and the varying costs of the seeds are accurately captured in the median cost data we use to calculate median cost for the APC. That is, we would expect that the cost associated with a bill would reflect the number of seeds used in a particular procedure and the median cost for that procedure overall would be an average of the varying numbers of seeds used by hospitals.

2. Special Revenue Code Packaging for Specific Types of Procedures

We proposed that the same packaging used for surgical procedures be used for corneal tissue implant procedures in APC 0244, Corneal Transplant, except that organ acquisition revenue codes and the revenue codes used to bill implantable devices are not packaged with corneal implants.

There are certain other diagnostic procedures with CPT codes that are similar to surgical procedures. The cost of these procedures (HCPCS codes 92980–92996, 93501–93505, and 93510–93536) reflects both the revenue code packaging for ambulatory surgical center (ASC) and other surgery, as well as the revenue code packaging for other diagnostic services.

A complete listing of the revenue codes that we used for purposes of calculating median costs of services are shown below in Table 2.

Table 2.—Packaged Services by Revenue Code

Surgery

250	Pharmacy
251	Generic
252	Nongeneric
257	Nonprescription Drugs
258	IV Solutions
259	Other Pharmacy
260	IV Therapy, general class
262	IV Therapy/pharmacy services
263	IV Therapy/drug supply/delivery
264	IV Therapy/supplies
269	Other IV Therapy
270	M&S supplies
271	Nonsterile supplies
272	Sterile supplies
274	Prosthetic/orthotic devices
275	Pacemaker drug
276	Intraocular lens source drug
278	Other implants
279	Other M&S supplies
280	Oncology
289	Other oncology

762 Observation room
810 Organ acquisition
290 Durable medical equipment
370 Anesthesia
379 Other anesthesia
390 Blood storage and processing
399 Other blood storage and processing
560 Medical social services
569 Other medical social services
624 Investigational device (IDE)
630 Drugs requiring specific identification, general class
631 Single source
632 Multiple
633 Restrictive prescription
700 Cast room
709 Other cast room
710 Recovery room
719 Other recovery room
720 Labor room
721 Labor
819 Other organ acquisition

Medical Visit

250 Pharmacy
251 Generic
252 Nongeneric
257 Nonprescription drugs
258 IV solutions
259 Other pharmacy
270 M&S supplies
271 Nonsterile supplies
272 Sterile supplies
279 Other M&S supplies
560 Medical social services
569 Other medical social services
630 Drugs requiring specific identification, general class
631 Single source drug
632 Multiple source drug
633 Restrictive prescription
637 Self-administered drug (insulin admin. in emergency diabetic coma)
700 Cast room
709 Other cast room
762 Observation room
942 Education/training

Other Diagnostic

254 Pharmacy incident to other diagnostic
280 Oncology
289 Other oncology
372 Anesthesia incident to other diagnostic
560 Medical social services
569 Other medical social services
622 Supplies incident to other diagnostic
624 Investigational device (IDE)
710 Recovery room
719 Other recovery room
762 Observation room

Radiology

255 Pharmacy incident to radiology
280 Oncology
289 Other oncology
371 Anesthesia incident to radiology
560 Medical social services
569 Other medical social services
621 Supplies incident to radiology
624 Investigational device (IDE)
710 Recovery room
719 Other recovery room
762 Observation room

All Other APC Groups

250 Pharmacy
251 Generic
252 Nongeneric
257 Nonprescription drugs
258 IV Solutions
259 Other pharmacy
260 IV Therapy, general class
262 IV Therapy pharmacy services
263 IV Therapy drug/supply/delivery
264 IV Therapy supplies
269 Other IV therapy
270 M&S supplies
271 Nonsterile supplies
272 Sterile supplies
279 Other M&S supplies
560 Medical social services
569 Other medical social services
630 Drugs requiring specific identification, general class
631 Single source drug
632 Multiple source drug
633 Restrictive prescription
762 Observation room
942 Education/training

3. Limit on Variation of Costs of Services Classified Within a Group

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost item or service within a group is more than 2 times greater than the lowest cost item or service within the same group. However, the Secretary may make exceptions to this limit on the variation of costs within each group in unusual cases such as low volume items and services. No exception may be made, however, in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act.

Based on the APC changes discussed above in this section of this preamble and our use of more current data to calculate the median cost of procedures classified to APCs, we reviewed all the APCs to determine which of them would not meet the 2 times limit. We use the following criteria when deciding whether to make exceptions to the 2 times rule for affected APCs:

- Resource homogeneity.
- Clinical homogeneity.
- Hospital concentration.
- Frequency of service (volume).
- Opportunity for upcoding and code fragmentation.

For a detailed discussion of these criteria, refer to the April 7, 2000 final rule (65 FR 18457).

The proposed rule set forth a list of APCs that we proposed to exempt from the 2 times rule based on the criteria cited above (66 FR 44690). In cases in which compliance with the 2 times rule appeared to conflict with a recommendation of the APC Advisory Panel, we generally proposed to accept the Panel recommendation. This was because Panel recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the data used to determine payment rates.

We received no comments on our proposal. The following is the final list of APCs we exempted from the 2 times rule. This list reflects the final APCs as recalibrated based on the updated 1999–2000 data base as well as the incorporation of 75 percent of the estimated cost of the pass-through devices (See section II.D).

List of APCs exempted from the ''two times'' requirement:

0001 Photochemotherapy
0004 Level I Needle Biopsy/Aspiration Except Bone Marrow
0043 Closed Treatment Fracture Finger/Toe/Trunk
0044 Closed Treatment Fracture/Dislocation Except Finger
0047 Arthroscopy without Prosthesis
0058 Level I Strapping and Cast Application
0060 Manipulation Therapy
0077 Level I Pulmonary Treatment
0093 Vascular Repair/Fistula Construction
0096 Non-Invasive Vascular Studies
0097 Cardiac Monitoring for 30 Days
0115 Cannula/Access Device Procedures
0121 Level I Tube Changes and Repositioning
0140 Esophageal Dilation without Endoscopy
0141 Upper GI Procedures
0142 Small Intestine Endoscopy
0147 Level II Sigmoidoscopy
0164 Level I Urinary and Anal Procedures
0165 Level III Urinary and Anal Procedures
0182 Insertion of Penile Prosthesis
0187 Placement/Repositioning Misc Catheters
0198 Pregnancy and Neonatal Care Procedures
0203 Level V Nerve Injections
0204 Level VI Nerve Injections
0207 Level IV Nerve Injections
0213 Extended EEG Studies and Sleep Studies, Level I

0215 Level I Nerve and Muscle Tests
0218 Level II Nerve and Muscle Tests
0233 Level II Anterior Segment Eye Procedures
0234 Level III Anterior Segment Eye Procedures
0237 Level III Posterior Segment Eye Procedures
0247 Laser Eye Procedures Except Retinal
0251 Level I ENT Procedures
0252 Level II ENT Procedures
0260 Level I Plain Film Except Teeth
0263 Level I Miscellaneous Radiology Procedures
0264 Level II Miscellaneous Radiology Procedures
0265 Level I Diagnostic Ultrasound Except Vascular
0279 Level I Angiography and Venography Except Extremity
0285 Positron Emission Tomography (PET)
0294 Level I Therapeutic Nuclear Medicine
0296 Level I Therapeutic Radiologic Procedures
0305 Level II Therapeutic Radiation Treatment Preparation
0322 Brief Individual Psychotherapy
0345 Level I Transfusion Laboratory Procedures
0354 Administration of Influenza/ Pneumonia Vaccine
0355 Level I Immunizations
0356 Level II Immunizations
0363 Otorhyinolaryngologic Function Tests
0364 Level I Audiometry
0373 Neuropsychological Testing
0600 Low Level Clinic Visits
0601 Mid Level Clinic Visits
0602 High Level Clinic Visits
0694 Level III Excision/Biopsy

4. Observation Services

Frequently, beneficiaries are placed in ''observation status'' in order to receive treatment or be monitored before making a decision concerning their next placement (that is, admit to the hospital or discharge to home). This occurs most frequently after surgery or a visit to the emergency department. In the proposed rule, we discussed the clinical and payment history of observation services. We also discussed at length the issues we considered in determining whether to make separate payment for observation services. For a more detailed discussion of our deliberations, see 66 FR 44690–91. After careful consideration, we proposed the following:

• To continue to package observation services into surgical procedures and most clinic and emergency visits.

• To create a single APC, APC 0339, Observation, to make separate payment for observation services for three medical conditions, chest pain, asthma, and congestive heart failure, when certain criteria (as described below) are met.

We also proposed to instruct hospitals that payment under APC 0339 for observation services would be subject to the following billing requirements and conditions:

• An emergency department visit (APC 0610, 0611, or 0612) or a clinic visit (APC 0600, 0601, or 0602) is billed in conjunction with each bill for observation services.

• Observation care is billed hourly for a minimum of 8 hours up to a maximum of 48 hours. We would not pay separately for any hours a beneficiary spends in observation over 24 hours, but all costs beyond 24 hours would be packaged into the APC payment for observation services.

• Observation time begins at the clock time appearing on the nurse's observation admission note. (We note that this coincides with the initiation of observation care or with the time of the patient's arrival in the observation unit.)

• Observation time ends at the clock time documented in the physician's discharge orders, or, in the absence of such a documented time, the clock time when the nurse or other appropriate person signs off on the physician's discharge order. (This time coincides with the end of the patient's period of monitoring or treatment in observation.)

• The beneficiary is under the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes, timed, written, and signed by the physician.

• The medical record includes documentation that the physician used risk stratification criteria to determine that the beneficiary would benefit from observation care. (These criteria may be either published generally accepted medical standards or established hospital-specific standards.)

• The hospital furnishes certain other diagnostic services along with observation services to ensure that separate payment is made only for those beneficiaries truly requiring observation care. We believe that these tests are typically performed on beneficiaries requiring observation care for the three specified conditions and they are medically necessary to determine whether a beneficiary will benefit from being admitted to observation care and the appropriate disposition of a patient in observation care. The diagnostic tests are as follows:

• For chest pain, at least two sets of cardiac enzymes and two sequential electrocardiograms.

• For asthma, a peak expiratory flow rate (PEFR) (CPT code 94010) and nebulizer treatments.

• For congestive heart failure, a chest x-ray, an electrocardiogram, and pulse oximetry.

We proposed to make payment for APC 0339 only if the tests described above are billed on the same claim as the observation service. (We did not propose to require telemetry and other ongoing monitoring services as criteria to make separate payment for observation services. Although these services are often medically necessary to ensure prompt diagnosis of cardiac arrhythmias and other disorders, we do not believe they are necessary to support separate payment for observation services.) In the proposed rule, we listed the following ICD–9–CM diagnosis codes that hospitals would be required to bill to receive payment for APC 0339:

For Chest Pain:

411.1 Intermediate coronary syndrome
411.81 Coronary occlusion without myocardial infarction
411.0 Postmyocardial infarction syndrome
411.89 Other acute ischemic heart disease
413.0 Angina decubitus
413.1 Prinzmetal angina
413.9 Other and unspecified angina pectoris
786.05 Shortness of breath
786.50 Chest pain, unspecified
786.51 Precordial pain
786.52 Painful respiration
786.59 Other chest pain

For Asthma:

493.01 Extrinsic asthma with status asthmaticus
493.02 Extrinsic asthma with acute exacerbation
493.11 Intrinsic asthma with status asthmaticus
493.12 Intrinsic asthma with acute exacerbation
493.21 Chronic obstructive asthma with status asthmaticus
493.22 Chronic obstructive asthma with acute exacerbation
493.91 Asthma, unspecified with status asthmaticus
493.92 Asthma, unspecified with acute exacerbation

For Congestive Heart Failure:

428.0 Congestive heart failure
428.1 Left heart failure
428.9 Heart failure, unspecified

In the proposed rule, we specified the following process to identify the appropriate median cost for APC 0339 (66 FR 44692). First, we identified in the 1999–2000 claims data all hospital outpatient claims for observation using revenue codes 760, 761, 762, and 769. We then selected the subset of these claims that were billed for patients with chest pain, asthma, and congestive heart failure. Because no standard method for coding these claims was in place in 1996, we identified all diagnosis codes that could reasonably have been used to classify beneficiaries as having chest pain, asthma, and congestive heart failure. We then verified that these beneficiaries received appropriate observation care for chest pain, asthma, or congestive heart failure by identifying the claims in which one or more of the tests identified above were performed. The median costs of these claims were used to establish the median costs of APC 0339.

Finally, we stated that we would consider medical research submitted to support the benefits of observation services for conditions other than those we had proposed. This information will assist us in determining whether these other conditions meet the criteria we used to select the three conditions we proposed to include in APC 0339.

We received a large number of comments on this proposal. Many commenters commended our proposal to pay separately for observation services. However, other commenters either had questions about or suggestions on revising our proposal. Those comments and our responses appear below.

Comment: We received comments requesting that we expand the list of conditions for which we would make a separate payment for observation services. Some commenters listed specific conditions that should be added to the list (for example, abdominal pain, atrial fibrillation, or pyelonephritis) while others asserted that any condition a physician thought required observation should qualify for separate payment. One commenter submitted medical literature as supportive evidence that we should expand our list of conditions. One commenter argued that developing a restrictive list of conditions for which separate payment would be made is inconsistent with the medical literature and with InterQual, which publishes the criteria used by Peer Review Organizations to assess whether admission to the hospital as an inpatient is necessary.

Response: We wish to clarify that our proposal merely specified a list of conditions for which we would make separate payment for observation services. For all other conditions, payment for observation services would be packaged into the APC in which those services were provided. For example, if a patient with syncope goes to the emergency room and receives emergency services and observation services, the payment to the hospital for the emergency visit includes payment for the observation service. The payment rate calculated for clinic and emergency visits includes the packaged costs of observation services to the extent that those costs were included on the visit bills.

We have reviewed the commenters' suggestions for additional conditions and the medical literature that they submitted in support of their requests. At this time, we are finalizing our proposal without expanding the list of conditions for which separate observation payment will be made. As noted in the proposed rule, we believe that chest pain, asthma, and congestive heart failure are the only conditions that require a well-defined set of hospital services that are distinctly different from the services provided in a clinic or emergency service. Thus, they are the services for which a separately payable observation period is clinically appropriate. Given the clinically improper use of observation care by hospitals in the recent past, we want to minimize the risk of future improper use while ensuring a valid medical benefit to the patient for appropriate medical care. Therefore, we believe it is premature to expand the conditions for which we will separately pay for observation services. We want to observe the effect of separate payment for this limited set of conditions to determine what clinical and payment issues arise before expanding the list of conditions. Furthermore, an essential issue for Medicare is that separate payment for observation be made only when those services are clearly distinct and separate from prolonged clinic or emergency department care and when observation provides a distinct clinical benefit that cannot be obtained by sending the patient home or admitting the patient to the hospital. We believe that the medical literature demonstrates such a benefit exists for patients with chest pain, congestive heart failure, and asthma.

We will continue to review this issue and any information that is provided to us. If we believe an expansion of the list of conditions is appropriate, we will include such a proposal in a future proposed rule.

Comment: An association of hospitals provided an explanation of their concept of ''rapid treatment,'' which they distinguished from observation. They defined observation as a service required by managed care contracts that involves only physiologic monitoring, frequent nursing assessment, and the patient's routine daily medication.

Response: This level of care would not qualify as an observation service, either packaged or separately paid, under Medicare. We require that during observation, patients be actively assessed and, if necessary, treated in order to determine if they should be admitted or may be safely discharged.

Comment: Several commenters pointed out that correct coding guidelines allow hospitals to code the reason for a patient's visit in any one of several fields on the claim including the principal diagnosis field, the secondary diagnosis field, and the admitting diagnosis field. These commenters suggested that facilities be allowed to report the appropriate diagnosis code supporting the provision of observation services in the admitting, principal, or secondary diagnosis field.

Response: We agree with the commenters and will ensure that our software is designed to allow this.

Comment: Commenters argued that additional ICD–9–CM diagnosis codes for chest pain, congestive heart failure, and asthma be added to the proposed list of diagnoses qualifying observation care for separate payment. These included: for asthma: 493.00, 493.10, 493.20, 493.90; for congestive heart failure: 391.8, 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; for chest pain: codes for weakness, shortness of breath, palpitations, rapid heart beat, and syncope. One commenter asked that we include codes for chronic obstructive pulmonary disease (COPD) on the list of qualifying diagnoses. One commenter believes that 428.1 and 428.9 are not to be used for congestive heart failure and should be deleted from the list.

Response: With regard to the comments to add diagnosis codes for asthma, our proposal included codes for status asthmaticus and acute exacerbations of asthma. The codes suggested by the commenters are used for chronic, stable asthma, or unspecified asthma. Our clinical judgment is that these patients do not require active observation care that meets our definition and, thus, a separate payment is not warranted. Therefore, we have not revised our list of qualifying diagnoses for asthma.

With regard to the suggested codes to be added for congestive heart failure, we agree with the commenters and are adding the codes to the list.

With regard to the suggested codes for chest pain, we note that 786.05, Shortness of breath, was included on our proposed list of qualifying codes. If a patient has one of the other suggested symptoms (weakness, palpitations, rapid heartbeat, and syncope), it would be appropriate to use one of the proposed codes as the diagnosis (for example, 413.9, other and unspecified angina). Therefore, we believe the list we proposed covers the additions suggested by the commenter.

With regard to the requested deletions of codes 428.1 and 428.9, we disagree. Code 428.1 is specified for use in patients with acute pulmonary edema and 428.9 is used for patients with congestive heart failure without a specific diagnosis and both codes are therefore appropriately included on the list.

Comment: Several commenters believe that dedicated observation units would not be financially viable if only three conditions qualified for payment.

Response: We want to emphasize that we are making payment for all observation services provided in the outpatient setting. Payment for observation services not meeting the requirements for separate payment in APC 0339 is included in the payment for the clinic or emergency department visit. That is, the payment for each clinic or emergency department visit contains a payment for packaged observation services. This means that hospitals are being paid for observation every time a clinic or emergency visit is billed.

Our policy of separate payment for certain observation services is not intended to increase the total amount of money paid for observation services. Instead, our policy redistributes payments into a separate APC; the relative weight of the new APC for observation services reflects costs that would otherwise be reflected in the relative weights for other relevant APCs. Thus, the payments for clinic and emergency visits are slightly lower than would have been the case had we not created a separate payment for observation. The only hospitals that could be disadvantaged are those that provided observation care for packaged conditions to an unusually large number of patients. Hospitals with large numbers of observation cases for chest pain, asthma, and congestive heart failure will benefit from our new policy. Hospitals with an average number of observation cases will be neither advantaged nor disadvantaged by our new policy.

Comment: Some commenters believe it is inappropriate ''not to pay for observation'' for other conditions. Others argued that because pulse oximetry, one of the diagnostic tests we identified as a condition of separate payment for congestive heart failure, is a packaged service, it is not paid for and therefore cannot be reported on the bill. This would place hospitals in a ''Catch-22'' situation because they would be required to report pulse oximetry to be paid separately for observation but could not report pulse oximetry because it is packaged.

Response: These comments reflect a misunderstanding of what it means for a service to be ''packaged.'' The concept is perhaps most clearly understood in terms of the anesthesia used during surgery. The costs of the anesthesia drugs and administration are associated with the surgery with which they were billed, and become part of the payment for the surgery. It is understood that anesthesia is paid for, but not paid for separately from the surgical procedure. Similarly, we packaged the cost of observation whenever it was billed. It is packaged into surgical procedures as well as clinic and emergency visits. Each time a hospital bills for a procedure or visit, any associated observation cost is recognized. Because, according to the literature, observation is billed in fewer than 6 percent of emergency room visits, the cost is not always readily identifiable. However, we wish to emphasize that it is important for hospital bills to show that observation was provided and the charges associated with it. This is because the charges for packaged services might affect outlier and transitional corridor payments, and are used to update the APC weights. Thus, hospitals should report pulse oximetry on the bill even though it is not separately payable.

Comment: Surgeons reported that hospitals, believing that observation is not payable, would not allow postoperative observation for patients such as those who have undergone mastectomy or thyroidectomy.

Response: Surgery performed in the outpatient setting should not, as a rule, require a period of postoperative observation. As provided in section 230.6E of the Medicare Hospital Manual, standing orders for observation following outpatient surgery is not a covered service. In addition, that section states that the availability of an outpatient observation unit at a hospital is not a reason to perform, on an outpatient basis, surgeries for which an overnight stay is anticipated.

Although an occasional surgical case may require a longer recovery period, as a rule, surgical outpatients should not require observation. We note, however, that to the extent that observation care is provided to surgical patients, the cost of that care is packaged into the payment for the surgical APC.

Comment: There were many comments on the list of diagnostic tests required for separate payment for observation services. Several commenters pointed out that nebulizer treatments, by definition, are not diagnostic. These commenters also noted that observation of asthma patients need not involve nebulizer treatments (that is, some patients are treated with intravenous steroids or inhalers). Others indicated that pulse oximetry is a routine test and is not usually coded. Other commenters were concerned that the required tests would not all be performed within the period of observation; that is, some tests might be performed in the emergency department before admission to observation status.

Response: The requirement that certain diagnostic tests be performed in order to receive separate payment for observation services reflects our concern that observation not be considered a way to keep a patient in a ''holding pattern.'' We are aware that some patients are considered to be in observation overnight when they are placed in a bed on a nursing unit, with vital signs taken every 4 hours. This is not the service we recognize as observation, which we define as an active treatment to determine if a patient's condition is going to require that he or she be admitted as an inpatient, or if it resolves itself so that the patient may be discharged. The services we included on the list of required treatment were designed to indicate that an active assessment of the patient was being undertaken. We believe this is consistent with the clinical practice of observation.

We agree that nebulizer treatments are not diagnostic, and, although, based on the experience of our clinical staff, are frequently used in acute asthma, they need not be used for every asthma patient receiving observation services. We agree that occasionally patients may use their own inhaler or be given intravenous medications without nebulizer treatments. Thus, we are not including this treatment on the final list of services required for separate payment of observation. As discussed above, pulse oximetry, although packaged, should be reported on the bill when furnished.

We agree that some of the required diagnostic testing (for example, cardiac enzymes) may be performed as part of the emergency or clinic visit before the

beneficiary is admitted to observation status. We will ensure that our software identifies when the required diagnostic tests were performed in the clinic or emergency department as well as diagnostic tests performed during the period of observation.

Comment: Several commenters claimed that requiring specific clinical interventions for observation care was an intrusion into the practice of medicine.

Response: We disagree with the commenters. We are setting conditions only for separate payment for observation. All observation care that does not meet the criteria for classification into APC 0339 will continue to be paid as part of the service into which it is packaged. In order to ensure that we are making separate payment only when it is warranted, we are providing as a condition for separate payment that a minimal number of appropriate diagnostic tests must be performed. The hospital will continue to receive packaged payment for observation care for beneficiaries who require such care but for whom the required tests were not performed.

As stated above, we are withdrawing the proposed condition of administering nebulizer treatments. We will allow either pulse oximetry or peak expiratory flow rate to be performed as a requirement to receive separate payment for observation of asthma patients. We are finalizing our requirements for chest pain and congestive heart failure. We note that none of the commenters had any clinical disagreement with the designation of these specific tests. Their only concern stemmed from the misconception that these tests would be required to be performed in order to receive payment for observation care. We will closely follow the impact of these requirements and, if we believe that changes are necessary, we will propose them in a future rule.

Comment: Several commenters argued that packaging the first 8 hours of observation was arbitrary and would be difficult to document. We also received comments that we should eliminate our minimum time requirement for observation or reduce it to 6 hours. The following reasons were given for these comments: asthma patients do not require 8 hours of observation; no evaluation and management (E/M) service lasts for more than 1 hour and 45 minutes; and emergency visits typically last 3–4 hours so any potential for abuse of observation would be reduced with a minimum time requirement of 6 hours because 6 hours does not overlap with the length of a typical emergency visit.

Response: We believe it is important to ensure that payment for clinic and emergency department services does not duplicate payments for observation. We also want to make clear that we do not consider a long emergency room visit to be ''observation.'' We believe that observation is a specific type of service that should be specifically ordered by a physician and should involve specific goals and a plan of care that is distinct from the goals and plan of care for an emergency or clinic visit. We believe that requiring 8 hours of care as a condition for separate payment of observation is reasonable and will minimize confusion for hospitals. We will be including the first 8 hours of observation care as a packaged service and make payment as part of the clinic or emergency visit with which it occurs. Therefore, the payment rate for emergency and clinic visit will reflect the extent to which patients are observed for less than 8 hours. Although occasionally patients with asthma may require less than 8 hours of observation, we believe that intensity and variety of services provided to patients with an acute asthma exacerbation or status asthmaticus who require 8 or more hours of observation is different from the service provided when they require less than 8 hours of observation. The less intensive services provided to asthma patients who require less than 8 hours of observation is appropriately paid for as part of an emergency or clinic visit. We note that we received no comments disagreeing with our minimum time requirement for patients with chest pain and congestive heart failure. Finally, we believe that a clear requirement of 8 hours will allow hospitals to prospectively develop clinical protocols and plans of care facilitating the appropriate use of observation services. However, we will closely monitor the impact of the 8-hour time requirement and, if appropriate, consider changes for a future proposed rule.

Comment: Commenters raised concerns about our requirement that physicians write progress notes in the medical record. They believe that admission and discharge notes are generally sufficient to document observation care. The commenters also raised questions about determining when observation starts and ends, with one commenter describing the proposed documentation requirement as ''rigid and inflexible.'' Others expected documentation to be difficult in hospitals without emergency department staff or house staff. One commenter stated that specific requirements for determining the time observation stops would not reflect the variety of methods hospitals and physicians have to document time in the medical record. Commenters asserted that the period of treatment and monitoring can continue beyond the time that a discharge order is written by the physician or taken off by the nurse.

One commenter discussed the difficulty in determining when a patient is ''moved to observation status'' and the need for physicians to be able to write orders specifying discharge at a ''future time.'' Several commenters expressed concerns about requiring documentation that the physician used risk stratification criteria to determine that the beneficiary would benefit from observation care because documenting use of risk stratification criteria would be burdensome and is not required for any other services.

Response: We appreciate these concerns and, although we are finalizing our proposal, we wish to clarify several aspects of these requirements to reassure commenters. With regard to writing progress notes, we wish to emphasize that the requirement is only to write ''appropriate'' progress notes. We understand that, in many cases, writing a progress note is unnecessary (because the admission and discharge notes are sufficient), while in other cases it is necessary to write progress notes because of the length and complexity of care provided or because of a change in the patient's condition. We wish to clarify that progress notes are not required in every case but only in those cases in which the physician deems it appropriate to write a progress note.

With regard to documenting the times that observation starts and ends, we have to balance the potential for improper billing of observation status against creating burdens for hospitals that will have to support their claims for observation treatment in the medical record. We believe that our policy strikes this balance appropriately. Typically both physicians' orders and nurses' removal of those orders are timed; therefore, we do not believe this requirement places a significant burden on physicians or hospitals because no change in the processes of care will be required. We do not believe that for chest pain, congestive heart failure, and asthma, orders are written for a future discharge time because those patients may not be discharged until treatment goals are met, and determining this requires current (not future) physician intervention (for example, to review lab tests or examine the patient).

An important reason we are requiring clocked time to determine the period of observation is because we want to minimize confusion and separate observation care from prolonged emergency or clinic visits. Our requirements will assist hospitals to prospectively ensure that observation is appropriately billed. Although it is possible that treatment and monitoring may continue for a significant period of time after a discharge order is written or taken off, we believe such an occurrence is the exception rather than the rule; additionally, it is frequently difficult to determine exactly when facility services are discontinued. One problem is that it is typical for those patients to remain in the observation area for a significant period of time after treatment is finished, most commonly because the patient is waiting for transportation home. As stated above, we need a bright line rule with regard to the stop time for observation.

With regard to documenting the use of risk stratification, we did not mean to require any extra documentation in the medical record. We just wish to put physicians and hospitals on notice as to what type of medical record evidence reviewers will use when reviewing claims for observation. We believe that a well-documented observation record will satisfy this requirement without any extra documentation. Therefore, we are clarifying that the manner in which documentation of risk stratification is made is at the discretion of the physician. As with all the criteria we are establishing for payment of APC 0339, we will monitor the effects of these requirements on the provision of observation care and consider making changes if appropriate.

Comment: We received a variety of comments asking for clarification as to how observation services should be reported; whether notes may be written by house staff or fellows; whether orders may be phoned in; whether additional diagnostic tests during observation would be paid for; how observation would be treated by local medical review policies; whether short inpatient stays for congestive heart failure and asthma would no longer be allowed; how billing would occur for patients who are admitted directly to a chest pain center without being seen in the emergency department; and whether payment for observation is made per hour or per day.

Response: Observation services should be tracked by the hour. If the number of hours is less than 8, then payment is packaged into the associated clinic or emergency visit. If more than 24 hours of observation are billed, payment for any time over 24 hours is packaged into the payment for 8 to 24 hours of observation. Therefore, the payment rate for observation will reflect those cases in which observation actually occurs for more than 24 hours. That is, just as the payment for emergency visits reflects payment for observation of up to 8 hours, so will payment for APC 0339 reflect payment for observation care up to 48 hours. Effective for services furnished on or after January 1, 2001, we have created a new HCPCS code for use with our new APC 0339 to help distinguish packaged observation form separately payable observation. The code is G0224, Observation care provided by a facility to a patient with CHF, chest pain, or asthma, minimum eight hours, maximum forty-eight hours. The previously available CPT codes for observation, 99234–99236, should continue to be used for packaged observation services.

With regard to house staff writing notes and orders, teaching physician rules apply to Part B payments for observation care. With regard to facility payments, observation may be billed if the notes are written by house staff. Physicians may phone in orders but if those orders are for admission or discharge to observation, they must be timed. Moreover, the physician must write admission and discharge notes in the medical record.

We note that we will pay separately for all nonpackaged diagnostic tests furnished to observation patients.

We will continue pay for inpatient admissions for chest pain, asthma, and congestive heart failure when appropriate and our observation payment policy is subject to local medical review policies.

With regard to direct admissions from physician offices, separate payment for observation will not be made unless a physician is present to order the initiation of observation services and to monitor the patient as clinically appropriate.

The following are the final requirements for billing G0244 and assignment to APC 0339.

The acceptable diagnosis codes are:

For Chest Pain

- 391.8 Other acute rheumatic heart disease
- 398.91 Rheumatic heart failure (congestive)
- 402.01 Malignant hypertensive heart disease with congestive heart failure
- 402.11 Benign hypertensive heart disease with congestive heart failure
- 402.91 Unspecified hypertensive heart disease with congestive heart failure
- 404.01 Malignant hypertensive heart and renal disease with congestive heart failure
- 404.03 Malignant hypertensive heart and renal disease with congestive heart and renal failure
- 404.11 Benign hypertensive heart and renal disease with congestive heart failure
- 404.13 Benign hypertensive heart and renal disease with congestive heart and renal failure
- 404.91 Unspecified hypertensive heart and renal disease with congestive heart failure
- 404.93 Unspecified hypertensive heart and renal disease with congestive heart and renal failure
- 411.1 Intermediate coronary syndrome
- 411.81 Coronary occlusion without myocardial infarction
- 411.0 Postmyocardial infarction syndrome
- 411.89 Other acute ischemic heart disease
- 413.0 Angina decubitus
- 413.1 Prinzmetal angina
- 413.9 Other and unspecified angina pectoris
- 786.05 Shortness of breath
- 786.50 Chest pain, unspecified
- 786.51 Precordial pain
- 786.52 Painful respiration
- 786.59 Other chest pain

For Asthma

- 493.01 Extrinsic asthma with status asthmaticus
- 493.02 Extrinsic asthma with acute exacerbation
- 493.11 Intrinsic asthma with status asthmaticus
- 493.12 Intrinsic asthma with acute exacerbation
- 493.21 Chronic obstructive asthma with status asthmaticus
- 493.22 Chronic obstructive asthma with acute exacerbation
- 493.91 Asthma, unspecified with status asthmaticus
- 493.92 Asthma, unspecified with acute exacerbation

For Congestive Heart Failure

- 428.0 Congestive heart failure
- 428.1 Left heart failure
- 428.9 Heart failure, unspecified

The required tests are as follows:

For chest pain, at least two sets of cardiac enzymes and two sequential electrocardiograms.

For asthma, a peak expiratory flow rate (PEFR) (CPT code 94010).

For congestive heart failure, a chest x-ray, an electrocardiogram, and pulse oximetry.

5. List of Procedures That Will Be Paid Only As Inpatient Procedures

Section 1833(t)(1)(B)(i) of the Act gives the Secretary broad authority to determine the services to be covered and paid for under OPPS. In the April 7, 2000 final rule, we defined a set of services that are typically provided only in an inpatient setting and, hence, would not be paid by Medicare under the OPPS (65 FR 18455). This set of services is referred to as the ''inpatient list.'' The inpatient list specifies those services that are appropriate to provide only in an inpatient setting and that, therefore, are only paid when provided in an inpatient setting. These are services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient.

At its February 2001 meeting, the APC Advisory Panel generally favored the elimination of the inpatient list. In the proposed rule, we stated that we disagreed with the position taken by the Panel and we proposed to continue the current policy of reviewing the HCPCS codes on the inpatient list and eliminating procedures from the list if they can be appropriately performed on the Medicare population in the outpatient setting. Our medical and policy staff, supplemented as appropriate by the APC Advisory Panel, would review comments submitted by the public and consider advances in medical practice in making decisions to remove codes from the list. We stated that we would continue to use the following criteria, which we discussed in the April 7, 2000 final rule, when deciding to remove codes from the list:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes we have already moved off the inpatient list (for example, the radiologic part of an interventional cardiology procedure).

In the proposed rule, we indicated that we would continue to update the list in response to comments as often as quarterly through program memoranda to reflect current advances in medical practice. We proposed no further changes to the inpatient list, which we set forth in Addendum E to the proposed rule.

Comment: Several specialty organizations, hospitals, and device manufacturers recommended that we remove certain procedures from the inpatient only list and assign them to APCs.

Response: We reviewed these requests in accordance with our previously published criteria and moved several of the procedures from the list. However, in our clinical judgment, the remainder of the procedures should not be moved. We are referring some of them to the APC Advisory Panel for review and further discussion at the next meeting. As noted in the proposed rule, we plan to continue updating the list on a quarterly basis, as needed. Set forth below is the list of procedures that commenters requested be moved off the inpatient list and the final action that we are taking in this rule.

Procedures That Remain Inpatient

- 34800—Endovascular repair of infrarenal abdominal aortic aneurysm or dissection
- 34802—Endovascular repair of infrarenal abdominal aortic aneurysm or dissection
- 34804—Endovascular repair of infrarenal abdominal aortic aneurysm or dissection
- 34808—Endovascular placement of iliac artery occlusion device
- 34812—Open femoral artery exposure for delivery of aortic endovascular prosthesis
- 34813—Placement of femoral-femoral prosthetic graft
- 34820—Occlusion during endovascular therapy
- 34825—Placement of proximal or distal extension prosthesis
- 34826—Infrarenal abdominal aortic aneurysm
- 33968—Removal of intra-aortic balloon assist device, percutaneous
- 44901—Incision and drainage of appendiceal abscess; percutaneous
- 49021—Drainage of peritoneal abscess or localized peritonitis; percutaneous
- 49041—Drainage of subdiaphragmatic or subphrenic abscess; percutaneous
- 49061—Drainage of retroperitoneal abscess; percutaneous
- 61624—Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)

Procedures Referred to the APC Advisory Panel

- 21390—Open treatment of orbital floor blowout fracture
- 27216—Percutaneous skeletal fixation of posterior pelvic ring fracture and/or dislocation
- 27235—Percutaneous skeletal fixation of femoral fracture, proximal end, neck
- 32201—Pneumonostomy; with percutaneous drainage of abscess or cyst
- 47490—Percutaneous cholecystostomy
- 64820—Sympathectomy, digital arteries, with magnification, each digit
- 92986—Percutaneous balloon valvuloplasty; aortic valve
- 92987—Percutaneous balloon valvuloplasty; mitral valve
- 92990—Percutaneous balloon valvuloplasty; pulmonary valve
- 92997—Percutaneous transluminal pulmonary artery balloon angioplasty; single vessel
- 92998—Percutaneous transluminal pulmonary artery balloon angioplasty; each additional vessel (list separately in addition to code for primary procedure)

Procedures Moved to APCs

- 23440—Resection or transplantation of long tendon of biceps (APC 0052)
- 23470—Arthroplasty, glenohumeral joint; hemiarthroplasty (APC 0048)
- 47011—Hepatotomy; for percutaneous drainage of abscess or cyst, one or two stages (APC 0005)
- 48511—External drainage, pseudocyst of pancreas; percutaneous (APC 0005)
- 49200—Excision or destruction by any method of intra-abdominal or retroperitoneal tumors or cysts or endometriomas (APC 0130)
- 50021—Drainage of perirenal or renal abscess; percutaneous (APC 0005)
- 58823—Drainage of pelvic abscess, transvaginal or transrectal approach, percutaneous (APC 0193)
- 61626—Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck extracranial, brachiocephalic branch) (APC 0081)
- 61791—Creation of lesion by stereotactic method, percutaneous, by neurolytic agent (e.g., alcohol, thermal, electrical, radiofrequency); trigeminal medullary tract (APC 0204)
- 63655—Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural (APC 0225)

6. Additional New Technology APC Groups

In the April 7, 2000 final rule, we created 15 new technology APC groups to pay for new technologies that do not meet the statutory requirements for

transitional pass-through payments and for which we have little or no data upon which to base assignment to an appropriate APC. APC groups 0970 through 0984 are the current new technology APCs. We currently assign services to a new technology APC for 2 to 3 years based solely on costs, without regard to clinical factors. This method of paying for new technologies allows us to gather data on their use for subsequent assignment to a clinically-based APC. Payment rates for the new technology APCs are based on the midpoint of ranges of possible costs.

After evaluating the costs of services in the new technology APCs, we proposed that APC 0982, which covers a range of costs from $2500 to $3500, be split into two APCs, as follows: APC 0982, which would encompass services whose costs fall between $2500 and $3000, and APC 0983, which would encompass those services whose costs fall between $3000 and $3500. APC 0984 would then encompass services whose costs fall between $3500 and $5000 and we would create a new APC, 0985, for services whose costs fall between $5000 and $6000. We believe that subdividing the current range of costs within APC 0982 would allow us to pay more accurately for the services in that cost range.

In section VI.G of this preamble, we describe several modifications and refinements to the criteria and process for assigning services to new technology APCs that we are implementing in this final rule.

We received no comments on adding a new technology APC group and have included this change in the final APCs. However, we note that in this final rule, we are making additional changes to the new technology APCs to improve our ability to pay appropriately for new technology services.

We are designating 16 additional APC groups, APCs 0706 through 0721, as new technology APCs and reassigning some services currently assigned to APC groups 0970 through 0985 so that, beginning with services furnished on or after January 1, 2002, there will be two parallel sets of new technology APCs. This is an administrative adjustment to distinguish between those new technology services designated with a status indicator of ''S'' and those designated ''T.'' The new APCs will allow us to assign to the same APC group procedures that are appropriately subject to a multiple procedure payment reduction (T) with those that should not be so discounted (S). Each set of new technology APC groups will have identical group titles, payment rates, and minimum unadjusted copayments, but a different status indicator. That is, the new technology APC groups 0970 through 0985 will, effective January 1, 2002, be assigned status indicator ''T'' and all services grouped in APCs 970 through 985 will be subject to the multiple procedure reduction. Each of the new technology APC groups 0706 through 0721 will be assigned status indicator ''S.'' Therefore, effective January 1, 2002, new technology services currently grouped under APC 0971, 0974, 0976, and 0981 are reassigned to APC 0707, 0710, 0712, and 0717, respectively, in order to retain the payment status indicator ''S.''

D. Recalibration of APC Weights for CY 2002

Section 1833(t)(9)(A) of the Act requires that the Secretary review and revise the relative payment weights for APCs at least annually beginning in 2001 for application in 2002. In the April 7, 2000 final rule (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group. Except for some reweighting due to APC changes, these relative weights continued to be in effect for 2001. (See the November 13, 2000 interim final rule (65 FR 67824–67827).)

To recalibrate the relative APC weights for services furnished on or after January 1, 2002 and before January 1, 2003, we proposed to use the same basic methodology that we described in the April 7, 2000 final rule to recalibrate the relative weights for 2002. That is, we would recalibrate the weights based on claims and cost report data for outpatient services. We proposed to use the most recent available data to construct the database for calculating APC group weights. For the purpose of recalibrating the proposed APC relative weights for 2002, the most recent available claims data are the approximately 98 million final action claims for hospital outpatient department services furnished on or after July 1, 1999 and before July 1, 2000. We matched these claims to the most recent cost report filed by the individual hospitals represented in our claims data. The APC relative weights would continue to be based on the median hospital costs for services in the APC groups.

The methodology we followed to calculate the final APC relative weights for CY 2002 is similar to the proposed except that there are now over 107 million final action claims and as discussed below in section VII of this preamble, we have incorporated a portion of pass-through device costs into device-related procedures. That action has increased the median costs for those procedures. The methodology for calculating the final APC relative weights is as follows:

- We excluded from the data approximately 16.2 million claims for those bill and claim types that would not be paid under the OPPS (for example, bill type 72X for dialysis services for patients with ESRD).
- Using the most recent available cost report from each hospital, we converted billed charges to costs and aggregated them to the procedure or visit level first by identifying the cost-to-charge ratio specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs) and then by matching the CCRs to revenue centers used on the hospital's 1999–2000 outpatient bills. The CCRs included operating and capital costs but excluded costs paid on a reasonable cost basis that are described elsewhere in this preamble.
- We eliminated from the hospital CCR data 283 hospitals that we identified as having reported charges on their cost reports that were not actual charges (for example, they make uniform charges for all services).
- We calculated the geometric mean of the total operating CCRs of hospitals remaining in the CCR data. We removed from the CCR data 67 hospitals whose total operating CCR exceeded the geometric mean by more than 3 standard deviations.
- We excluded from our data approximately 2.1 million claims from the hospitals that we removed or trimmed from the hospital CCR data.
- We matched revenue centers from the remaining universe of approximately 89.1 million claims to CCRs of 5,672 hospitals.
- We separated the 89.1 million claims that we had matched with a cost report into two distinct groups: single-procedure claims and multiple-procedure claims. Single-procedure claims were those that included only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims included more than one HCPCS code that could be mapped to an APC. There were approximately 39.9 million single-procedure claims and 49.2 million multiple-procedure claims.
- To calculate median costs for services within an APC, we used only single-procedure bills. We did not use multiple-procedure claims because we are not able to specifically allocate charges or costs for packaged items and services such as anesthesia, recovery room, drugs, or supplies to a particular

procedure when more than one significant procedure or medical visit is billed on a claim. Use of the single-procedure bills minimizes the risk of improperly assigning costs to the wrong procedure or visit.

• For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. If the appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or to the hospital's overall cost-to-charge ratio for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as not paid under the OPPS (for example, laboratory, ambulance, and therapy services).

• To calculate the per-service costs, we used the charges shown in the revenue centers that contained items integral to performing the service. These included those items that we previously discussed as being subject to our proposed packaging provision. For instance, in calculating the surgical procedure cost, we included charges for the operating room, treatment rooms, recovery, observation, medical and surgical supplies, pharmacy, anesthesia, and donor tissue, bone, and organ. For medical visit cost estimates, we included charges for items such as medical and surgical supplies, drugs, and observation in those instances in which it is still packaged. See sections II.C.1 and II.C.2 of this preamble for a discussion and complete listing of the revenue centers that we used to calculate per-service costs. In addition, for device-related procedures, we incorporated 75 percent of the estimated cost of the pass-through device into the per-service costs.

• We standardized costs for geographic wage variation by dividing the labor-related portion of the operating and capital costs for each billed item by the current FY 2002 hospital inpatient prospective payment system wage index published in the **Federal Register** on August 1, 2001 (65 FR 40038). We used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. A more detailed discussion of wage index adjustments is found in section III of this preamble.

• We summed the standardized labor-related cost and the nonlabor-related cost component for each billed item to derive the total standardized cost for each procedure or medical visit.

• We removed extremely unusual costs that appeared to be errors in the data using a trimming methodology analogous to what we use in calculating the DRG weights for the hospital inpatient PPS. That is, we eliminated any bills with costs outside of 3 standard deviations from the geometric mean.

• After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC, including, to the extent possible, the proposed APC changes described elsewhere in this preamble.

• We calculated the median cost, weighted by procedure volume, for each APC.

• Using the weighted median APC costs, we calculated the relative payment weights for each APC. We scaled all the relative payment weights to APC 0601, Mid-level clinic visit, because it is one of the most frequently performed services in the hospital outpatient setting. This approach is consistent with that used in developing relative value units for the Medicare physician fee schedule. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601, to derive the relative payment weight for each APC. The median cost for APC 0601 is $54.00.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes and wage index changes be made in a manner that ensures that aggregate payments under the OPPS for 2002 are neither greater than nor less than the aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2001 relative weights to aggregate payments using the CY 2002 final weights. Based on this comparison, in this final rule we are making an adjustment of 0.945 to the weights; that is, each weight is reduced by this factor (the scaler). The final weights for 2002, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B of the final rule.

We note that in the proposed rule, we inadvertently applied the weight adjustment factor of 1.022 to the relative weights of the new technology APCs. This was incorrect. The payment rates for the new technology APCs are based on the mid-point of the cost range represented by the APC. Therefore the payment rates should be static from year to year. In this final rule, the payment rates for APCs 0970–0985 correctly reflect no adjustment.

Comment: We received numerous comments regarding HCPCS codes and APC groups for which the payment rate proposed for 2002 is lower than the current payment rate. Commenters expressed concern that the proposed decrease in payment would have adverse effects both on beneficiary access to services and hospital solvency. Many commenters suggested that a lower rate was a data or a calculation error and requested that a particular weight be confirmed. Many commenters stated that because the lower proposed payment rate was inadequate to pay hospital costs for the service, we should adjust the rate to a more appropriate level.

Response: As explained above, the methodology we used to recalibrate the final 2002 relative weights is essentially the same methodology that we followed to recalibrate the weights in the August 24, 2001 proposed rule, with the exception of the additional step of folding pass-through device costs into certain base APC costs. (We discuss the reason for this additional step in the November 2, 2001 OPPS final rule (66 FR 55857).)

In both the proposed rule and this final rule, the relative weights for the APC groups change for two reasons: The use of more recent claims data, and the statutory requirements governing how payment for all services under the OPPS must be determined.

The use of more recent claims data: We calibrated the relative weights published in the April 7, 2000 final rule using, as required by the statute, claims from 1996 and data from the most recent available hospital cost reports. These relative payment weights were implemented on August 1, 2000 and they have remained largely unchanged throughout 2001. In the August 24 proposed rule, we proposed to use the same basic methodology to recalibrate the weights that we described in the April 7, 2000 final rule (65 FR 18482). But we also proposed to use the most recent available data, rather than 1996 data, to construct the database for calculating APC group weights. For 2002, the most recent data are from final action claims for hospital outpatient services furnished beginning July 1, 1999 through June 30, 2000. In recalibrating the final weights for 2002, we had the benefit of data from additional claims that had not been received when we recalibrated the relative payment weights for the August 24, 2001 proposed rule. We matched these claims to the most recent cost report filed by the various hospitals represented in the claims data. Hospital costs reflected in claims for the period July 1, 1999 through June 30, 2000 have

changed from those taken from 1996 claims.

Statutory requirements governing how payment for OPPS services is to be determined. Section 1833(t)(9)(B) of the Act requires that estimated spending for services covered under the OPPS be neither greater nor less than it would have been had we not recalibrated the APC weights nor made changes in the APC groups. Because of this, the weights and, therefore, the payment rates for a specific service may increase or decrease depending on the change in charges hospitals report for that service relative to the change in charges hospitals report for other outpatient services.

Under any prospective payment system or fee schedule that bases rates on a system of relative weights within limits imposed by a budget neutrality requirement, some weights will increase and others will decrease from year to year. A decrease in the relative weight for an APC is the result of a decrease in the relative level of charges for the services in that APC that hospitals reported for the period from July 1, 1999 through June 30, 2000, compared to the relative level of charges the same hospitals reported for all other outpatient services furnished during the same period. In addition, the application of the budget neutrality adjustment required by section 1833(t)(9)(B) of the Act will further decrease a relative weight if the adjustment is less than 1.000.

In this final rule, some weights are lower than what we had proposed. The further lowering of weights for some APCs is the result of our incorporating a portion of the cost of pass-through devices into the basic costs of the APCs with which the devices are associated. As we explained in the final rule published on November 2, 2001 (66 FR 55857), the portion of the pass-through device costs that were incorporated into APC costs are not evenly distributed among the APCs, but rather are concentrated in a relatively small number of APCs that include the procedures that use pass-through devices. Whereas the weights of these APCs have increased as a result of the added device costs, the weights for all APCs that do not include device costs have decreased.

In preparing the weights for this final rule, we were particularly attentive to APCs such as APC 0169, Lithotripsy, APC 0245, Level I Cataract Procedures without IOL Insert, and APC 0246, Cataract Procedures with IOL Insert, about which commenters had expressed concern. As a result, we have a high level of confidence in the appropriateness of the weights that are in this final rule. Therefore, we are not increasing the relative weight or payment rate for an APC group simply because its payment is lower in 2002 than it was in 2001 nor are we reducing the relative weight or payment rate for an APC group simply because its payment is higher in 2002 than it was in 2001.

III. Wage Index Changes

Under section 1833(t)(2)(D) of the Act, we are required to determine a wage adjustment factor to adjust for geographic wage differences, in a budget neutral manner, that portion of the OPPS payment rate and copayment amount that is attributable to labor and labor-related costs.

We used the May 4, 2001 proposed Federal fiscal year (FY) 2002 hospital inpatient PPS wage index (66 FR 22646) to make wage adjustments in determining the proposed payment rates set forth in the proposed rule. We also proposed to use the final FY 2002 hospital inpatient wage index to calculate the final CY 2002 payment rates and coinsurance amounts for OPPS. We received no comments on this issue and are implementing our proposed policy in final.

The final FY 2002 hospital inpatient wage index published in the August 1, 2001 **Federal Register** (66 FR 39828) is reprinted in this final rule as Addendum H, Wage Index for Urban Areas; Addendum I, Wage Index for Rural Areas; and Addendum J, Wage Index for Hospitals That Are Reclassified. Those wage index values will be used to calculate the OPPS payment rates and coinsurance amounts for calendar year (CY) 2002.

IV. Copayment Changes

We note that in section 1833(t) of the Act, the terms ''*copayment*'' and ''*coinsurance*'' appear to be used interchangeably. To be consistent with CMS usage, we make a distinction between the two terms throughout this preamble. We are making conforming changes to part 419 of the regulations to reflect the following usage:

- ''*Coinsurance*'' means the percent of the Medicare-approved amount that beneficiaries pay for a service furnished in the hospital outpatient department (after they meet the Part B deductible).
- ''*Copayment*'' means the set dollar amount that beneficiaries pay under the OPPS. For example, if the payment rate for an APC is $200 and the beneficiary is responsible for paying $50, the copayment is $50 and the coinsurance is 25 percent.

A. BIPA 2000 Coinsurance Limit

As discussed in section I.C of this preamble, certain provisions of BIPA 2000 affect beneficiary copayment amounts under the OPPS. Section 111 of the BIPA added section 1833(t)(8)(C)(ii) of the Act, to accelerate the reduction of beneficiary copayment amounts, providing that, for services furnished on or after April 1, 2001 and before January 1, 2002, the national unadjusted coinsurance for an APC cannot exceed 57 percent of the APC payment rate. The statute provides for further reductions in future years so that the national unadjusted coinsurance for an APC cannot exceed 55 percent in 2002 and 2003, 50 percent in 2004, 45 percent in 2005, and 40 percent in 2006 and thereafter.

We implemented the reduction in beneficiary copayments for 2001 effective April 1, 2001 through changes to the OPPS PRICER software used to calculate OPPS payments to hospitals from the Medicare Program and beneficiary copayments.

We proposed to revise § 419.41 to conform the regulations text to this provision.

We received no comments on this proposal and are implementing the required 55 percent limit on the national unadjusted coinsurance rate of the final APCs. We are also adopting as final the proposed changes to the regulations text.

B. Impact of BIPA 2000 Payment Rate Increase on Coinsurance

Under the statute as enacted by BBA 1997, APC payment rates for 2001 were to be based on the payment rates for 2000 increased by the inpatient hospital market basket percentage increase minus 1 percentage point; however, section 401 of the BIPA 2000 increased APC payment rates for 2001 to reflect an update based on the full market basket percentage increase. The Congress intended for the increased payment to be in effect for the entire calendar year 2001; however, to provide us sufficient time to make the change, the Congress adopted a special payment rule for 2001. Under section 401(c) of the BIPA, the payment rates in effect for services furnished on or after January 1, 2001 and before April 1, 2001 are the rates as determined under the statute prior to the enactment of BIPA. For services furnished on or after April 1, 2001 and before January 1, 2002 the payment rates reflect the full market basket update and are further increased by 0.32 percent to account for the timing delay in implementing the full market basket update for 2001. The 0.32 percent

increase is a temporary increase that applies only to the period April 1 through December 31, 2001 and is not considered in updating the OPPS conversion factor for 2002. The increase in APC payment rates for 2001 was implemented effective April 1, 2001 through changes to the OPPS PRICER software. We proposed to revise § 419.32 to conform to the statute.

The section 401 increase to the APC payment rates affected beneficiary copayments in several ways. In cases for which the beneficiary coinsurance was already based on 20 percent of the APC payment rate, the increase in the APC payment rate caused a corresponding increase in the copayment for the APC. For all other APCs, the copayment amount remained at the same level. In addition, because the minimum copayment amount for an APC, which is the lowest amount a provider may elect to charge if it chooses to reduce copayments for an APC, is based on 20 percent of the APC amount, the increase to an APC payment rate under section 401 of BIPA resulted in an increase to the minimum copayment amount for each APC.

We received no comments on this issue, and we are implementing the changes to the regulations text in final.

C. Coinsurance and Copayment Changes Resulting From Change in an APC Group

National unadjusted copayment amounts for the original APCs that went into effect on August 1, 2000 were, by statute, based on 20 percent of the national median charge billed for services in the APC group during calendar year 1996, trended forward to 1999, but could be no lower than 20 percent of the APC payment rate. Although the BBA 1997 specified how copayments were to be determined initially, the statute does not specify how copayments are to be determined in the future as the APC groups are recalibrated or as individual services are reclassified from one APC group to another. In the proposed rule, we provided the method we intend to apply in determining copayments for new APCs (that is, those created after 2001) and for APCs that are revised because of recalibration and reclassification. We also discussed the issues we considered in developing a proposed approach to be used in determining copayments for new or revised APCs.

The following describes how we proposed to determine copayment amounts for new and revised APCs for 2002 and subsequent years:

1. If a newly created APC group consists of services that were not included in the 1996 data base or whose charges were not separately calculated in that data base (that is, the services were excluded or packaged) the unadjusted copayment amount would be 20 percent of the APC payment rate.

2. If recalibrating the relative payment weights results in an APC having a decrease in its payment rate for a subsequent year, the unadjusted copayment amount will be calculated so that the coinsurance percentage for the APC remains the same as it was before the payment rate decrease. For example, assume the APC had a payment rate of $100 and an unadjusted copayment amount of $50, resulting in a coinsurance percentage of 50 percent. If the new payment rate for the APC is lowered to $80, the copayment amount is calculated using the prior coinsurance percentage of 50 percent; therefore, the new copayment amount would be 50 percent of $80 or $40.

3. If recalibrating the relative payment weights results in an APC having an increase in its payment rate for a subsequent year, the unadjusted copayment amount would be calculated so that the copayment dollar amount for the APC remains the same as it was before the payment rate increase. That is, the unadjusted copayment amount would not change. For example, assume the APC had a payment rate of $100 and an unadjusted copayment amount of $60 (a coinsurance percentage of 60 percent). If the new payment rate for the APC is increased to $150, the unadjusted copayment amount would remain at $60 (a coinsurance percentage of 40 percent).

4. If a newly created APC group consists of services from two or more existing APCs, the unadjusted copayment amount would be calculated based on the lowest coinsurance percentage of the contributing APCs. For example, a new APC is created by moving some or all of the services from two existing APCs into the new APC. Assume that one contributing APC had a payment rate of $100 and an unadjusted copayment amount of $40, a coinsurance percentage of 40 percent. Assume the other contributing APC had a payment rate of $150 and an unadjusted copayment amount of $75, a coinsurance percentage of 50 percent. If the new APC had a payment rate of $130, the unadjusted copayment amount for the new APC would be based on a coinsurance percentage of 40. The unadjusted copayment amount for the new APC would be 40 percent of $130, or $52.

These changes will in general reduce beneficiary copayment for services in affected APCs. For 2002, we believe the size of these changes will be modest. If in the future the size of such changes appears likely to be large, we may revisit this policy.

5. If an APC payment rate is increased due to a conversion factor update, the unadjusted copayment amount for the APC would not change.

We received no comments on this proposal. Therefore, we are implementing the proposed methodology for calculating copayment amounts in this final rule.

V. Outlier Policy Changes

For OPPS services furnished before January 1, 2002, section 1833(t)(5)(D) of the Act explicitly authorizes the Secretary to apply the outlier payment provision based upon all of the OPPS services on a bill. We exercised that authority and, since the beginning of the OPPS on August 1, 2000, we have calculated outlier payments in the aggregate for all OPPS services that appear on a bill. However, beginning January 1, 2002, we proposed to calculate outlier payments based on each individual OPPS service. That is, we proposed to revise the aggregate method that we are currently using to calculate outlier payments and begin to determine outliers on a service-by-service basis for OPPS services furnished on or after January 1, 2002.

In the proposed rule, we discussed in detail the difficulties we faced with calculating outliers based on individual services. We also discussed possible solutions to those problems including requiring hospitals to submit separate bills for each OPPS service and allocating the charges for any packaged service among the individual OPPS services that appear on the bill. We stated that we prefer using one of the approaches that would allocate packaged charges among the APCs on a bill to avoid disruptive billing changes. We proposed that charges be allocated to each OPPS service based on the percent the APC payment rate for that service bears to the total APC rates for all OPPS services on the bill.

We also proposed to convert charges to costs for calculating outlier payments by continuing to apply a single overall hospital-specific cost-to-charge ratio instead of applying hospital-specific departmental cost-to-charge ratios. In the proposed rule, we explained that, for purposes of calculating outlier payments under the OPPS, the use of departmental cost-to-charge ratios is not feasible given currently available information because we do not have a way of defining, in a uniform manner that is accurate for all hospitals, which departmental cost-to charge ratio to

apply to a revenue code billed by a hospital. We also explained that collecting the data necessary to make it feasible to use departmental cost-to-charge ratios would impose significant burden and administrative costs on hospitals and our contractors. We then stated that given that outliers represent only 2 to 3 percent of total OPPS expenditures, we believe that the increased accuracy in calculating outlier payments that we could gain would not be sufficient to justify the significant additional administrative burden and cost that would be required. For this reason, we proposed to continue to apply a single hospital-specific outpatient cost-to-charge ratio to convert billed charges to costs for calculating outlier payments.

As explained in the April 7, 2000 final rule (65 FR 18498), we set a target for outlier payments at 2.0 percent of total payments. We also explained that, for purposes of simulating payments to calculate outlier thresholds, we set the parameters for determining outlier payments as if the target were 2.5 percent. We believed that it would be likely that using simulation 1996 claims data would overstate the percentage of payments that would be made. Based on the simulations, we set a threshold for outlier payments at 2.5 times the claim cost and a payment percent of 75 percent of the cost above the threshold for both 2000 and 2001.

In setting the proposed CY 2002 outlier threshold and payment percentage, we accounted for the change to service level rather than claim level outlier calculation. We proposed to set the target for outlier payment at 2.0 percent as we had for CY 2001. We believe that the claims data we are using to set the 2002 payment rates reflect much better coding of services than did the 1996 data so we set the proposed threshold and proposed payment percentage based on simulations of payments so that the percentage of outlier payments under the simulations was 2.0 percent, rather than 2.5 percent as we did in simulating payments to set the outlier criteria for the April 7, 2000 final rule. Based on our simulations, the proposed threshold for 2002 is 3 times the service costs and the proposed payment percentage for costs above that threshold is set at 50 percent. Based on the simulations using the updated claims data from July 1, 1999 to June 30, 2000, the final threshold for 2002 is 3 times the service costs and the final payment percentage for costs above that threshold is set at 50 percent (the same as the proposed thresholds).

We received many comments on our proposed changes to the outlier policy, which are summarized below along with our responses.

Comment: Several commenters expressed concern that we proposed to increase the outlier threshold while lowering the payment percentage without providing sufficient analysis in the proposed rule to document and justify these changes. A number of commenters contended that the quality of the data is not sufficient to justify these dramatic changes and urged us to maintain the current threshold and payment percentage until better data become available. One commenter recommended that we either furnish hospitals with the information that explains the significant changes, providing an additional opportunity to comment, or maintain the current threshold and payment percentage amounts. Another commenter stated that, in the annual proposed and final rules for hospital inpatient PPS, the data to support any modifications to outlier payments are presented in detail and the commenter believes we should include similar information in the annual proposed and final OPPS rules.

Response: In the April 7, 2000 final rule (65 FR 18498), we described the general methodology that we use to set the outlier threshold and payment percentage. We use historical claims data and simulate payments for those claims by applying the payment rates and policies for the upcoming year. We calibrate the threshold and payment percentage by applying an iterative process in which we try different combinations of thresholds and payment percentages until an appropriate combination results in outlier payments under the simulation equal to the target percentage (for purposes of the simulation) of total OPPS payments under the simulation.

There are two major sources of the changes between the threshold and payment percentage for 2001 and these proposed 2002. First, the outlier payment simulations for the proposed rule reflected the proposed change in the outlier payment policy from a bill-level calculation to service-level calculation. Second, the outlier payment simulations for the proposed rule were based on updated claims data which were considerably more recent than the 1996 claims we used previously. We believe that the updated data reflect more accurate coding of the outpatient services hospitals furnished compared to the 1996 data.

When updated data or a change in policy (or, as in this case, both) dictate a significant change in the outlier parameters, we believe it is, in general, a better policy to adjust both the threshold and the outlier payment percentage. For 2002, an adjustment made only to the threshold amount would greatly limit the number of services that would qualify for an outlier payment. Conversely, an adjustment only to the outlier payment percentage would have significantly decreased the amount of the outlier payment made for the services that do qualify. By adjusting both of the parameters, we hope to strike a balance. That is, for 2002 as compared to 2001, we do not wish to drastically lower the number of services qualifying for outlier payment nor do we wish to significantly decrease the amount of payment hospitals may receive for services that qualify as outliers. Based on this premise, we both raised the outlier threshold and decreased the payment percentage in order to prevent, to the extent possible, large changes in the outlier payments made to hospitals.

Comment: One commenter stated that, because we provided no data to demonstrate that the target for CY 2001 would be exceeded, we should provide that if the proposed changes are put into place and actual outlier payments in 2002 are significantly less than the 2002 outlier target, the ''shortfall'' from 2001 and 2002 will be made up by increased outlier payments in subsequent years.

Response: The outlier threshold and payment percentage are determined each year based on our best estimate of what threshold and payment percentage are needed to achieve a certain level of outlier payments. For example, for CY 2002, we set the threshold and payment percentage based on estimates so that outlier payments are projected to equal 2.0 percent of total OPPS payments.

Section 1833(t)(5)(C) of the Act requires that the outlier payment estimate for a year be made by the Secretary before the beginning of the year. Consistent with our outlier policies in other prospective payment systems, we will not adjust outlier payments in subsequent years to account for an underestimation (or overestimation) of outlier payments in a previous year. The statute does not provide for such an adjustment. We set the outlier policies prospectively, using the best available data. Outlier payments, like many aspects of a prospective payment system, reflect estimates, and we believe it would be inappropriate to adjust the outlier payments (upward or downward) for a given year simply because an estimate for a previous year ultimately turned out to be inaccurate. If we underestimate or overestimate the percentage of outlier payments, the divergence of our estimate from actual experience may

provide information that might help us improve future estimates, but it would have no direct effect on the amount of outlier payments for any following year.

Comment: One commenter suggested that we lack reliable data on actual claims experience that are critical in determining which hospitals are receiving outlier payments and for which specific services. The commenter believes that once such data become available, they can be used to improve the APC system, reducing the overall need for outliers and to refine the outlier methodology to target outlier payments as most appropriate.

Response: As coding on outpatient claims improves, the median costs we use to calculate APC weights and, ultimately, APC payment rates will also more accurately reflect the resources associated with furnishing the services within each APC. It is possible that this may reduce the incidence of outlier payments for specific services as well as decrease the need for outlier payments across all services.

Comment: One commenter pointed out that the increase in the outlier threshold and the decrease in the percent of the excess costs that will be paid as an outlier payment are based on an outlier target of 2.0 percent of estimated total OPPS payments. In order to not penalize hospitals that treat high cost cases, the commenter recommended that the outlier target be set at 3.0 percent of estimated total OPPS payments.

Response: Section 1833(t)(5)(C) of the Act limits projected outlier payments for years prior to 2004 to no more than 2.5 percent of projected total OPPS payments. For CY 2002, we proposed to set the target for outlier payments at 2.0 percent. Although we could increase that amount to 2.5 percent, we have chosen not to do so because increasing the outlier target percentage would require a corresponding decrease to APC payment amounts due to budget neutrality. Given the decrease in many of the APC payment rates that results from the incorporation of 75 percent of device pass-through costs into the APCs (see section II.D. of this preamble), we believe it is appropriate not to increase the outlier target percentage so that there is no additional reduction in the APC payments. Once we have claims data that reflect payments made under the OPPS, our analysis of those data may lead us to revise our policy of setting the outlier target below the limit allowed.

Comment: One commenter estimated that the proposed changes in the threshold and the payment percentage would reduce outlier payments by as much as 50 percent. Several other commenters claimed that the proposed changes would result in drastic cuts in outlier payments to certain community mental health centers (CMHCs) in Louisiana and Mississippi. These commenters contended that the payment reductions would be so severe that CMHCs would be forced to close, thereby eliminating services for the seriously and persistently mentally ill. These commenters requested that the CY 2002 outlier payments for CMHCs continue to be calculated using the CY 2001 outlier threshold and payment percentage.

Another commenter asked that we provide data on outlier payments made since the implementation of the OPPS to provide greater information about the impact of outliers on cancer care. The commenter stated that, in the area of cancer care, hospital outpatient departments often provide the only access point for patients needing complex therapies or new therapies not yet specifically recognized by the coding system and outlier payments provide an important safeguard against any adverse impact of providing this care. The commenter specifically requested information on how the outlier payments have been applied to cancer patients across the country. If actual outlier payments are less than the 2.0 percent target, the commenter urged us to direct more of the outlier monies to cancer care or apply any difference between projected and actual outlier amounts to the transitional pass-through payments for drugs and devices.

Response: As discussed above, the difference between the 2001 and proposed 2002 outlier threshold and payment percentage arises from the use of newer claims data and the change to a service-level rather than claim-level outlier payment calculation. In accordance with section 1833(t)(5) of the act, we set a ''fixed'' threshold that applies to all OPPS services. Thus, we apply a uniform threshold to all OPPS services in a given calendar year; the statute does not provide for different thresholds for different classes of providers or different types of OPPS services. Similarly, we set the payment percentage prospectively before the beginning of each year and apply it to all OPPS services qualifying for outlier payments in that year.

Currently, we do not have adequate data for OPPS claims to perform a useful analysis of actual outlier payments under the OPPS, but we expect to discuss information on actual outlier payments in future regulation documents after sufficient information becomes available.

For the suggestion concerning the redistribution of outlier payments to pass-through drugs and devices, we note that the statute provides for both the outlier and transitional pass-through payments and establishes the 2.5 percent limits on those payments for the years before 2004 (when the limit for outliers increases to 3.0 percent and the limit for transitional pass-throughs decreases to 2.0 percent). Thus, we do not have the administrative authority to make the change that this commenter has recommended. Rather, legislative action would be required to make any of these changes.

Comment: Although some commenters were in favor of calculating outlier payments on an individual service basis, several commenters requested that we reconsider our proposal and recommended that we continue to use the aggregate bill method. Another commenter believes that the increased specificity gained under the proposed outlier methodology would not offset the additional costs and administrative burden to hospitals of making information system changes necessary to calculate and verify outlier payments. One commenter asserted that multiple service claims are not used in calculating the APC relative weights because we are unable to accurately allocate packaged items and services when more than one service is billed on a claim. The commenter is concerned that the same problem would occur with the proposed methodology for paying outliers and recommends that, to avoid inappropriate outlier payments, we should continue to calculate outliers on a claim-level basis until an equitable method of assigning packaged costs is developed.

Another commenter believes that the current methodology more accurately meets the intent of outlier payments, which is to pay facilities for unusual expenses incurred on behalf of patients, not specific line items or individual services. The commenter stated that the allocation of charges to develop service-by-service outliers presents an administrative problem to those hospitals that must significantly alter their systems in order to monitor and audit their payments.

Several commenters expressed concern that the proposed service-level approach could result in very few services qualifying for additional payment and asked for a delay in the policy. One hospital association requested a delay so it would have an opportunity to evaluate CYs 2000 and 2001 data to better understand the impact the change would have on its member hospitals. Another hospital

association believes that the data that are currently available (that is, data for services furnished prior to implementation of the OPPS) may not accurately reflect the financial impact of the proposed change and asked for a delay in calculating service-level outliers until OPPS data are available and can be provided to the hospital industry for analysis. Several commenters urged us to delay implementation of service-level outlier calculations until hospitals and fiscal intermediaries had adequate time to perform systems testing related to the change.

Response: We believe that calculating outliers on a service-by-service basis is the most appropriate way to calculate outliers for outpatient services. Outliers on a bill basis requires both the aggregation of costs and the aggregation of OPPS payments thereby introducing some degree of offset among services; that is, the aggregation of low cost services and high cost services on a bill may result in no outlier payment being made. While service-based outliers are somewhat more complex to administer, under this method, outlier payments will be more appropriately directed to those specific services for which a hospital incurs significantly increased costs. We are revising the outpatient PRICER program to calculate outliers on a service-by-service basis, and we do not anticipate that our contractors will have any significant problems being able to calculate outlier payments under this revised policy.

Comment: Two commenters requested clarification concerning how outlier payments would be calculated on a service-by-service basis in the case of multiple surgical procedures appearing on the same claim when all of the surgical charges are combined into a single line on the claim. One commenter stated that if hospitals will be required to change the practice of combining surgical charges for all procedures on a single line item, they may require significant resources to comply with such a change.

Response: The commenters raise a valid concern. When a hospital performs several surgical procedures during the same operative session, it is an acceptable billing practice to show the entire charge for use of the operating room or treatment room on the line with one of the surgical HCPCS codes and zero charges on the lines with the remaining surgical HCPCS codes. We do not intend to require that hospitals change this practice. Hospitals will continue to have the option of splitting out the charges among the individual surgical procedures based on the resources that are attributable to each procedure or they may show a single combined charge with one of the surgical HCPCS codes and zero charges with the others. If the hospital chooses the latter option, in calculating outliers on a service-by-service basis, we will allocate the combined operating or treatment room charge among all of the surgical procedures on the bill. The charges will be allocated to each surgical procedure based on the proportion that the APC payment for the procedure bears to the total APC payments for all surgical procedures performed on that day.

Comment: One commenter supported calculating outliers on a service-by-service basis and agreed with using an overall cost-to-charge ratio, but disagreed with the proposal to allocate packaged services. Several commenters asserted that while it is not possible to directly assign packaged services to a payable procedure in all cases, it is possible in some cases. As an example, the commenters stated that on a claim with a surgical procedure and a visit or diagnostic service, it would be logical and reasonable to assign anesthesia, recovery room, and device charges completely to the surgical procedure, instead of allocating a portion to the visit or diagnostic service.

Another commenter recommended that we modify our proposal for allocating packaged services and develop a set of rules to directly assign the packaged services for those obvious situations when there is a clear relationship of the packaged item or service to the payable service or procedure.

Response: We believe that the policy the commenters are recommending is problematic. For example, anesthesia and recovery room services are not limited to surgical procedures but may also be billed with certain diagnostic procedures. Although we agree that we may in the future be able to improve the allocation of packaged services for a service-level outlier calculation, we also must be careful that the calculation does not become so complex that hospitals are unable to understand how their outlier payments have been determined. Therefore, we are not adopting the commenter's suggestion. We will however continue to analyze possible refinements to this policy.

Comment: One commenter acknowledged the complexities we would face in using a cost report line-specific method of calculating the cost-to-charge ratios (CCRs) for outlier payments but believes the issue warrants further study. The commenter contends that using line-specific CCRs is the only way to ensure that outlier payments are equitable on a service level.

Response: We agree with the commenter that applying appropriate departmental cost-to-charge ratios (CCRs) would generally be more accurate than using an overall outpatient CCR. However, as discussed above and in the proposed rule, it is currently unfeasible to use departmental cost-to-charge ratios for purposes of outlier payments under the OPPS because we currently do not have the necessary information. We continue to believe that the increased accuracy that would be achieved by use of departmental CCRs would not justify the significant administrative burden that would be placed on both hospitals and fiscal intermediaries.

Comment: A number of commenters raised concerns about the hospital-specific CCRs we have used since the beginning of OPPS to calculate outlier payments as well as transitional pass-through payments and interim transitional corridor payments. The commenters raised issues relating to the accuracy of CCR calculations, the basis of future CCR updates, and the timing of CCR updates.

Response: We are working on instructions to our fiscal intermediaries that will address both how and when the CCRs will be revised and updated and those instructions will be published in a forthcoming program memorandum.

VI. Other Policy Decisions and Proposed Changes

A. Change in Services Covered Within the Scope of the OPPS

Section 1833(t)(1)(B) of the Act defines the term ''covered OPD services'' that are to be paid under the OPPS. ''Covered OPD services'' are ''hospital outpatient services designated by the Secretary'' and include ''inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (1) is entitled to benefits under Part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (2) is not so entitled'' (that is, ''Part B-only'' services). ''Part B-only'' services are certain ancillary services furnished to inpatients for which the hospital receives payment under Medicare Part B. These services, which are specified in section 3110 of the Medicare Intermediary Manual and section 2255C of the Medicare Carriers Manual include diagnostic tests; X-ray and radioactive isotope therapy; surgical dressings, splints and casts; prosthetic

devices; and limb braces and trusses and artificial limbs and eyes.

In the April 7, 2000 final rule, we included inpatient ''Part B-only'' services within the definition of services payable under the OPPS (68 FR 18543). In the proposed rule, we discussed some hospitals' concerns about the administrative burden and prohibitive costs they would incur if they were to change their billing systems to accommodate OPPS requirements solely to receive payment for ''Part B-only'' services. We proposed to revise § 419.22 by adding paragraph (r) to exclude Part B-only services that are furnished to inpatients of hospitals that do no other billing for hospital outpatient services under Part B from payment under the OPPS.

We noted that under this proposed revision of the regulations, hospitals with outpatient departments would continue to bill under the OPPS for Part B-only services that they furnish to their inpatients. However, a hospital that does not have an outpatient department would be unable to bill under the OPPS for any Part B-only service the hospital furnished to its inpatients because those services would not fall within the scope of covered OPD services. If a hospital with no outpatient department is currently billing under the OPPS, the hospital would have to revert to its previous payment methodology for services furnished on or after January 1, 2002. That methodology would be an all-inclusive rate for hospitals paid that way prior to the implementation of OPPS and reasonable cost for other hospitals.

We received several comments on this proposal, which are summarized below.

Comment: Several commenters requested that the proposed change be made retroactive to the implementation of OPPS on August 1, 2000. These commenters observed that, without retroactive effect, the hospitals would be unable to bill for inpatient ancillary services provided to beneficiaries with Part B-only coverage during the period from August 1, 2000 until January 1, 2002. Another commenter contended that the proposed policy should have retroactive effect. The commenter raised two alternative reasons for this contention. One was that section 1833(t)(1)(B)(ii) of the Act should not have been interpreted to apply to inpatients who have exhausted their Part A coverage because of the 190-day lifetime limit on inpatient psychiatric days, because the statutory language refers only to hospital inpatients who have ''exhausted benefits for inpatient hospital services during a spell of illness.'' The other was that, allegedly, CMS had never designated through formal regulations those Part B services that are subject to the OPPS. Until such a rule is adopted, the commenter contended, no service provided on an inpatient basis to beneficiaries with Part B-only coverage can be subject to OPPS.

Response: Contrary to the assertion of the commenter, we have in fact designated those Part B services to be covered under the OPPS through formal regulations. In the April 7, 2000, final rule, we specifically included services furnished to inpatients who have exhausted their Part A benefits in the list of ''Services Included Within the Scope of the Hospital Outpatient PPS,'' and provided examples of those services (65 FR 18444). The statutory language gives the agency broad authority to define the services that are to be included under the OPPS. The statute broadly includes both ''hospital outpatient services designated by the Secretary'' and ''inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (1) is entitled to benefits under Part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (2) is not so entitled'' within the definition.

We designated Part B-only services as OPPS services through notice and comment rulemaking, and the policy has been in effect since the inception of OPPS. As discussed in the proposed rule, representatives of hospitals approached us *after* publication of the April 7, 2000 final rule to express concerns about the policy. We have considered those concerns, and we are changing the policy prospectively. We believe not only that applying the policy change on a prospective basis only is fair (particularly given that the current policy was established through notice and comment rulemaking) but also that applying the policy change on a retroactive basis would constitute impermissible retroactive rulemaking.

Comment: Several commenters requested that CMS clarify that those hospitals to which this change applies may resume billing under the per diem based methodology that they employed prior to the implementation of OPPS.

Response: As we stated in the proposed rule (66 FR 44699), ''If a hospital with no outpatient department is currently billing under the OPPS, the hospital would have to revert to its previous payment methodology for services furnished on or after January 1, 2002. That methodology would be an all-inclusive rate for hospitals paid that way prior to the implementation of OPPS and reasonable cost for other hospitals.'' The hospitals to which this change applies may therefore resume billing under the per diem or reasonable cost methodology that was applicable to them prior to the implementation of the OPPS.

Comment: One commenter asked that we recognize the situation of two other classes of hospitals. Some hospitals that have outpatient departments submit claims for only a limited range of outpatient services under Part B. Other hospitals have outpatient departments (for example, for children's psychiatric services) but submit no claims under Medicare Part B. The commenter contended that these hospitals do not have the capacity to bill for the full range of inpatient ancillary services under the OPPS.

Response: We believe that it is very important to restrict this exception to those hospitals that do not provide Medicare Part B services through an outpatient department. As stated in the April 7, 2000 final rule, in developing a hospital OPPS, we ''wanted to ensure that all services furnished in a hospital outpatient setting will be paid on a prospective basis.'' (65 FR 18442.) We believe that hospitals that have outpatient departments and that bill for some outpatient services under Part B should also be paid for the services in question under the OPPS. Therefore, those hospitals will not be excluded from billing under the OPPS. On the other hand, the exception will apply to those hospitals that do not bill under Medicare Part B, even if they have outpatient departments; that is, they do not treat Medicare beneficiaries in their outpatient departments.

Comment: Several commenters requested that CMS clarify whether the proposed provision in § 419.22(r) of the regulations would include therapy services (for example, physical therapy) so that the State psychiatric hospitals included in the exception could resume billing therapies at the per diem all-inclusive rate. The commenters pointed out that these services are currently included in the list of ancillary services under section 3110 of the Medicare Intermediary Manual and section 2255C of the Medicare Carrier Manual. In the proposed rule, CMS specified that the Part B-only services to which the proposed exception would apply were ancillary services listed in those manual sections, but did not specifically list the therapy services in the proposed rule. Some of these commenters raised the same question about diagnostic laboratory services, which CMS had also not specifically listed in the preamble text, but which are included in the list of ancillary services under section 3110

of the Medicare Intermediary Manual and section 2255C of the Medicare Carrier Manual.

Response: Section 1833(t)(1)(B)(iv) of the Act specifically excludes outpatient physical therapy, outpatient speech-language pathology, and outpatient occupational therapy from the definition of services payable under the OPPS. Therefore, we specifically did not include them in the list of Part-B only services to which the exception would apply in the proposed rule. These services are subject to fee schedules that were established prior to the OPPS.

We agree with the commenters that diagnostic laboratory services are included in the list of ancillary services that are excluded from the OPPS under this policy.

B. Categories of Hospitals Subject To and Excluded from the OPPS

Under § 419.20(b), certain hospitals in Maryland that qualify under section 1814(b)(3) of the Act for payment under the State's payment system are excluded from the OPPS. Critical access hospitals (CAHs), which are paid under a reasonable cost-based system as required under section 1834(g) of the Act, are also excluded. In addition, we stated in the April 7, 2000 final rule that the outpatient services provided by the hospitals of the Indian Health Services (IHS) will continue to be paid under separately established rates. We also noted that we intended to consult with the IHS and develop a plan to transition these hospitals into OPPS. With these exceptions, the OPPS applies to all other hospitals that participate in the Medicare program.

In the proposed rule, we noted that under the statute, hospitals located in Guam, Saipan, American Samoa, and the Virgin Islands are excluded from the hospital inpatient PPS. We proposed to revise § 419.20 of the regulations by adding paragraph (b)(3) to exclude these hospitals from OPPS consistent with their treatment under inpatient PPS. In addition, we proposed to revise paragraph (b)(4) of that section to include the hospitals of the IHS to clarify that they are excluded from OPPS until we develop a plan to include them. We noted that it might also be possible to include the hospitals in the territories in the OPPS in the future.

We received one comment on this proposal, as set forth below.

Comment: A commenter asked for clarification about the meaning of ''hospital of the Indian Health Service'' in the context of our proposal. The commenter requested that CMS define the term to include several classes of hospitals, not only those owned and operated by the IHS, but also those that are operated by Tribes and Tribal organizations, but owned or leased by the IHS.

Response: We agree with the commenter that clarification of the term ''hospital of the Indian Health Service'' is appropriate, and we are taking this opportunity to do so. Specifically, we will use here the definition at 42 CFR 413.65(l), where the term is defined to include facilities and organizations that, on or before April 7, 2000, furnished only services that were billed as if they were furnished by a hospital operated by the IHS or by a Tribe and that are: owned and operated by the Indian Health Service; owned by a Tribe or Tribal organization but leased from the Tribe or Tribal organization by the IHS under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes; or owned by the Indian Health Service but leased and operated by the Tribe or Tribal organization under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

C. Conforming Changes: Additional Payments on a Reasonable Cost Basis

Hospitals subject to the OPPS are paid for certain items and services that are outside the scope of the OPPS on a reasonable cost or other basis. Payments for the following services are made on a reasonable cost basis or otherwise applicable methodology:

a. The direct costs of medical education as described in § 413.86.

b. The costs of nursing and allied health programs as described in § 413.85.

c. The costs associated with interns and residents not in approved teaching programs as described in § 415.202.

d. The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based payment for teaching physicians under § 415.160.

e. The costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c).

f. Bad debts for uncollectible deductible and coinsurance amounts as described in § 413.80(b).

g. Organ acquisition costs paid under Part B.

Interim payments for these services are made on a biweekly basis and final payments are determined at cost report settlement.

We proposed to revise § 419.2(c) to make conforming changes that reflect the exclusion of these costs from the OPPS rates.

We received one comment on this proposal, as follows.

Comment: The commenter supported the clarification, but requested a statement concerning how CMS will ensure that the appropriate interim biweekly payments for these services are made.

Response: We are working on appropriate operating instructions to our intermediaries with directions to ensure that the appropriate interim payments for these items and services are made.

D. Hospital Coding for Evaluation and Management Services

In the April 7, 2000 final rule, we emphasized the importance of each facility accurately assessing the intensity, resource use, and charges for evaluation and management (E/M) services, in order to ensure proper reporting of the service provided. In the proposed rule, we stated that we understand that facilities have developed several different systems for determining resource consumption to assign proper E/M codes. Some of these systems are based on clinical (''condition'') criteria, and others are based on weighted scoring criteria. We continue to believe that proper facility coding of E/M services is critical for assuring appropriate payments. In order to achieve this, we are interested in developing and implementing a standardized coding process for facility reporting of E/M services. This process could include the use of current HCPCS codes or the establishment of new HCPCS codes in conjunction with guidelines for facility coding.

In the proposed rule, we solicited comments from hospitals and other interested parties on this issue. We stated that we would submit these comments to the APC Advisory Panel and ask for the Panel's recommendations regarding the development and implementation of a facility coding process for E/M services. We will review both the public comments and the recommendations from the Panel and propose a coding process in the proposed rule for 2003.

E. Annual Drug Pricing Update

1. Payment for Drugs and Biologicals

Under the OPPS, we pay for drugs and biologicals in one of three ways.

a. Packaged Payment. As we explained in the April 7, 2000 final rule, we generally package the cost of drugs, biologicals, and pharmaceuticals into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished (65 FR 18450). No separate payment is made under the OPPS for drugs, biologicals, and pharmaceuticals whose costs are packaged into the APCs with which they are associated.

b. Transitional Pass-Through Payments for Eligible Drugs and Biologicals. As we also explained in the April 7, 2000 final rule and in section VII of this preamble, the BBRA 1999 provided for special transitional pass-through payments for a period of 2 to 3 years for the following drugs and biologicals:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act;
- Current drugs and biologic agents used for treatment of cancer;
- Current radiopharmaceutical drugs and biological products; and
- New drugs and biologic agents in instances where the item was not being paid for as a hospital outpatient service as of December 31, 1996, and where the cost of the item is ''not insignificant'' in relation to the hospital outpatient PPS payment amount.

In this context, ''current'' refers to those items for which hospital outpatient payment was being made on August 1, 2000, the date on which the OPPS was implemented. A ''new'' drug or biological is a product that was not paid as a hospital outpatient service before January 1, 1997 and for which the cost is not insignificant in relation to the payment for the APC to which it is assigned. In the proposed rule, we discussed in detail the statutory basis and payment methodology for transitional pass-through payments for drugs and biologicals. In addition, we included an illustration of the payment methodology.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act, that is, 95 percent of the applicable average wholesale price (AWP). Section 1833(t)(6)(D)(i) of the Act also sets the amount of additional payment for pass-through-eligible drugs and biologicals (the pass-through payment amount). The pass-through payment amount is the difference between 95 percent of the applicable AWP and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Therefore, as we explained in the April 7, 2000 final rule (65 FR 18481), in order to determine the correct pass-through payment amount, we first had to determine the cost that was packaged for the drug or biological within its related APC. In order to determine this amount, we used the following methodology, which we also explained in the April 7, 2000 final rule.

When we implemented the OPPS on August 1, 2000, costs for drugs and biologicals eligible for transitional pass-through payment were, to the extent possible, not included in the payment rates for the APC groups into which they had been packaged prior to enactment of the BBRA 1999. That is, to the extent feasible, we removed from the APC groups into which they were packaged, the costs of as many of the pass-through eligible drugs and biologicals as we could identify in the 1996 claims data. Then, we assigned each drug and biological eligible for a pass-through payment to its own, separate APC group, the total payment rate for which was set at 95 percent of the applicable AWP.

Next, in order to establish the applicable beneficiary copayment amount and pass-through payment amount, we had to determine the cost of the pass-through eligible drug or biological that would have been included in the payment rate for its associated APC had the drug or biological been packaged. We used hospital acquisition costs as a proxy for the amount that would have been packaged, based on data taken from an external survey of hospital drug costs. (See the April 7, 2000 final rule (65 FR 18481).) We imputed the acquisition cost for the various drugs and biologicals in pass-through APCs by multiplying their applicable AWP by one of the following ratios. The following ratios are based on the survey data, and they represent, on average, hospital drug acquisition cost relative to AWP:

- For drugs with one manufacturer (sole-source), the ratio of acquisition cost to AWP equals 0.68.
- For drugs with more than one manufacturer (multi-source), the ratio of acquisition cost to AWP equals 0.61.
- For drugs with more than one manufacturer and with generic competitors, the ratio of acquisition cost to AWP equals 0.43.

In accordance with section 1833(t)(7) of the Act, we base beneficiary copayment amounts for pass-through drugs only on that portion of the drug's cost that would have been included in the payment amount for an associated APC had the drug been packaged. Therefore, having determined the hospital acquisition cost of the drug based on the ratios described above, we multiply the acquisition cost by 20 percent to calculate the beneficiary copayment for the pass-through drug or biological APCs. Finally, to calculate the actual pass-through payment amount, we subtract the hospital acquisition cost from the applicable 95 percent of AWP. The Medicare program payment is the sum of the acquisition cost and the pass-through amount, less the beneficiary copayment amount.

To illustrate this payment methodology, consider a current sole source drug with an average wholesale price (AWP) of $100 per dose. Under section 1842(o) of the Act, the total allowed payment for the drug is $95, that is, 95 percent of AWP. We impute the cost of the drug based on survey data, which indicate hospital acquisition costs for this type of drug on average to be 68 percent of its AWP (or $68). In the absence of the pass-through provisions, this cost would be packaged into the APC payment for the procedure or service with which the drug or biological is furnished. Therefore, we define the beneficiary coinsurance as 20 percent of the imputed cost of $68, resulting in a copayment amount of $13.60. The pass-through payment amount is $27 (the difference between 95 percent of AWP ($95) and the portion of the APC payment that is based on the cost of the drug ($68)). The total Medicare program payment in this example equals $81.40 (cost of the drug in the APC ($68) less beneficiary copayment ($13.60), plus pass-through payment ($27)). In the proposed rule, we clarified that, for purposes of calculating transitional pass-through payment amounts, we make no distinction between new and current drugs and biologicals. Rather, we assume that drugs and biologicals defined as ''new'' under section 1833(t)(6)(A)(iv)(I) of the Act, that is, for which payment was not being made as of December 31, 1996, nonetheless replace or are alternatives to drugs, biologicals, or therapies whose costs would have been reflected in our 1996 claims data and, thus, have been packaged into an associated APC. Therefore, we assume that our imputed acquisition cost, based on the external survey data, represents that portion of the APC payment attributable to new as well as current drugs and biologicals. For that reason, we are discontinuing use of the payment status indicator ''J'' that we introduced in the November 13,

2000 final rule to designate a ''new'' drug/biological pass-through. Instead, we stated that we would assign payment status indicator ''G'' to both current and new drugs that are eligible for pass-through payment under the OPPS. (Addendum D of this final rule lists the definition of the OPPS payment status indicators.)

c. Separate APCs for Drugs Not Eligible for Transitional Pass-Through Payment. There are some drugs and biologicals for which we did not yet have adequate cost data that are not eligible for transitional pass-through payments. Beginning with the April 7, 2000 final rule, we created separate APCs for these drugs and biologicals to allow separate payment so as not to discourage their use where appropriate.

We based the payment rate for these APCs on median hospital acquisition costs. To determine the hospital acquisition cost for the drugs, we imputed a cost using the same ratios of drug acquisition cost to AWP used in connection with calculating acquisition costs for transitional pass-through drug payments. That is, we multiplied the AWP for the drug by the applicable ratio (sole, multi, or generic source) based on data collected in an external survey of hospital drug acquisition costs.

We set beneficiary copayment amounts for these drugs APCs at 20 percent of the imputed acquisition cost. We use status indicator ''K'' to denote the APCs for drugs, biologicals, and pharmaceuticals that are paid separately from and in addition to the procedure or treatment with which they are associated yet are not eligible for transitional pass-through payment. Refer to Addendum A of this final rule to identify these APCs.

2. Annual Drug Pricing Update

a. Drugs Eligible for Pass-Through Payments. We used the AWPs reported in the Drug Topics Red Book to determine the payment rates for the pass-through drugs and biologicals. In the proposed rule we referred to a discussion in the November 13, 2000 interim final rule. When we developed that interim final rule, it was our understanding that, although there are quarterly updates to the AWPs in the Red Book, the annual update is published in April of each year. It was our intention to update the AWPs for drugs each July 1, the quarter following the annual publication, and we did use the April 2001 version of the Red Book to update the APC rates for drugs eligible for pass-through payments. The pass-through payment rates for drugs and biologicals updated for 2001 went into effect July 1, 2001 (Program Memorandum A–01–73, issued on June 1, 2001).

We found that doing an update for all the pass-through drugs and biologicals at mid-year was disruptive to both our computer systems and pricing software. Thus, we proposed to update the APC rates for drugs that are eligible for pass-through payments in 2002 using the July 2001 or October 2001 version of Red Book. The updated rates effective January 1, 2002 would remain in effect until we implement the next annual update in 2003, when we would again update the AWPs based on the latest quarterly version of the Red Book. This would place the update of pass-through drug prices on the same calendar year schedule as the other annual OPPS updates.

b. Drugs in Separate APCs Not Eligible for Pass-Through Payments. We used the conversion factor published in the November 13, 2000 final rule (65 FR 67827) to update, effective January 1, 2001, the APC rates for the drugs that are not eligible for pass-through payments that are in separate APCs. We also made payment adjustments to these APC groups effective April 1, 2001, as required by section 401(c) of the BIPA, which sets forth a special payment rule that had the effect of providing a full market basket update in 2001.

For 2002, we proposed to recalibrate the weights for the APCs for drugs that are not pass-through items and make the other adjustments applicable to the APC groups that we discuss in sections III, IV, and VIII of this preamble.

We received several comments on our discussion of the payment for drugs under the OPPS. These comments are summarized below.

Comment: One commenter expressed concern that the ''three methodologies for drug payment reductions in the proposed rule'' may not take into account the most recent data. The commenter requested an estimate of the magnitude of the expected reduction, and the data used to develop the estimate.

Response: We did not propose three methodologies for drug payment reductions in the proposed rule. Rather we described, in greater detail than we have previously, the three methods by which drug costs are paid under the OPPS. In the final rule that we published on November 2, 2001 (66 FR 55857), we announced that we would be implementing a reduction in the payments made for one category of drugs, namely those drugs that qualify for transitional pass-through payments. As we described in that final rule, this reduction is applied on a uniform basis to all pass-through payments (including payments for devices) and is required to enforce a statutory limit on the size of those estimated payments relative to the estimate of all spending under the OPPS.

Comment: One commenter was confused by an apparent discrepancy between our description of how the pass-through payment amount for a drug is calculated and our example of how the amount is calculated. The description indicated that the beneficiary coinsurance is subtracted from the applicable 95 percent of AWP and imputed acquisition cost, but the example did not include this subtraction.

Response: We regret that the written description was not entirely clear. The example was accurate. The pass-through payment is the difference between 95 percent of AWP and imputed acquisition cost. The beneficiary coinsurance is 20 percent of the imputed acquisition cost. The Medicare program payment is the pass-through amount, plus the imputed acquisition cost, minus the beneficiary copayment. Total payment to the hospital is the pass-through amount, plus the imputed acquisition cost, plus the beneficiary copayment. In our example (see above), the AWP for the drug was $100, and 95 percent of AWP was thus $95. The imputed acquisition cost for the drug was 68 percent of AWP, or $68. Beneficiary coinsurance was 20 percent of $68, or $13.60. The Medicare program payment is $27 (the pass-through amount), plus $68 (the imputed acquisition cost), minus $13.60 (the beneficiary copayment), for a total of $81.40. Total payment to the hospital is $81.40 (the Medicare program payment) plus $13.60 (the beneficiary copayment), for a total of $95.

Comment: Several commenters objected that our drug pricing is based on annual updates using 6-month old data and on ratios of drug acquisition costs to AWP that derive from outdated and limited data. Some of these commenters objected to the use of the acquisition cost study to establish the ratios of drug acquisition costs to AWP. One commenter asked that CMS clarify why the new system is too complex to undertake quarterly updates of drug prices.

Response: We are placing the updates for the drugs that are eligible for pass-through payments on the same annual update schedule as the rest of the OPPS. We will always use the most recent available version of the Red Book in doing this update. Assuming that the October Red Book becomes available in time for use in the final rule establishing the annual OPPS updates, our drug

pricing may be based on data that are only 3 months old when it becomes effective. In any event, it is not unusual for updates to prospective payment systems to reflect data that are 6 months old or older. We have always considered the use of the study-derived ratios of drug costs to AWP to be an interim measure until we are able to obtain data on hospitals' actual costs for drugs from claims. We anticipate having this data available for use in setting payment rates for 2003. Revisions to our payment systems require a long lead-time, and thus it would be very difficult to implement more than one update in a year. We note that rate-based payment systems are commonly updated annually, and we see no compelling reason why the update of drug prices under the OPPS should be updated more frequently than the other payment rates under the system.

Comment: Several commenters requested more information about the methodology that CMS uses to compute payment rates for drugs, radiopharmaceuticals, and biologicals, particularly those that are not sole source.

Response: We employ the methodology provided in 42 CFR § 405.517(c) to determine the payment rates. Specifically, we compute the median price of each drug, radiopharmaceutical, or biological, using the median price of the generic versions or the lowest of the prices of the brand versions from the Red Book. (For drugs with both generic and brand manufacturers, we use the lower cost of the two.) For the denominator, we employ measures of dosage and concentration that are compatible with the HCPCS code descriptor. We also consider route of administration (for example, intravenous or perenteral) and dose. As an example, if drug A has a descriptor of 10 mg As the dose, we usually utilize the AWP for 5 mg and 10 mg doses, but not for 25 mg or 50 mg doses. This is because the latter two doses could not be administered to provide a 10 mg dose. If drug B has a descriptor for 25 mg injection and the drug is manufactured in 5 mg per ml, 25 mg per ml, and 50 mg per ml concentrations, we would utilize the AWP for the 25 and 50 mg per ml concentrations, but not the 5 mg per ml concentration. This is because we would not expect a beneficiary to receive a 5 ml injection, which would be necessary to utilize the lowest concentration dose to provide 25 mg of the drug at the 5 mg per ml concentration.

However, we lack precise information for many drugs in the Red Book concerning the size of vials/ampules and the numbers of vials/ampules per packaging. In these cases, we are unable to employ this methodology, and we simply use the list price. We are continuously seeking further information on these drugs, and we will revise the pricing as we obtain additional information.

Comment: Several commenters called our attention to instances in which the Medicare payment is higher than the cost for certain drugs, especially radiopharmaceuticals.

Response: We thank the commenters for bringing these cases to our attention. We have experienced some difficulty in determining appropriate payment rates for radiopharmaceuticals due to several factors. First, the Red Book lacks information concerning the dosage per vial after the elements are compounded to create the radioactive substance, the numbers of doses that can be obtained per vial, and the cost per vial when more than one dose may be given from the vial. Nuclear medicine experts have informed us that multiple doses for multiple patients can often be obtained with one vial and that we have often unnecessarily assumed the cost for the entire vial. At the same time, there are circumstances in which an entire vial is appropriately charged for one patient. We have made the appropriate modifications for those agents that have been identified to us. We welcome any additional information that would help us to ensure that payment rates reflect as accurately as possible the cost and usage of these agents.

Comment: One commenter requested that CMS clarify whether repackaged products are included in its calculations.

Response: There is no separate calculation for any repackaging process. We use only AWPs to calculate drugs and biological prices.

Comment: One commenter asked us to clarify how we pay for the pharmacy overhead costs associated with administering drugs. The commenter expressed concern that the data in the survey of drug costs did not capture these costs.

Response: For the drugs paid for under the OPPS, hospitals can bill both for the drug and for the administration of the drug. The overhead cost is captured in the administration codes, along with the costs of all drugs that are not paid for separately. Each time a drug is billed with an administration code, the total payment thus includes the acquisition cost for the billed drug, the packaged cost of all other drugs, and the overhead costs.

F. Definition of Single-Use Devices

Our definition of a device eligible for pass-through payment includes a criterion whereby eligible devices are used for one patient only and are single use (65 FR 47674, August 3, 2000). In the November 13, 2000 interim final rule, we stated, in response to a comment, that additional pass-through payments would not be made for devices that are reprocessed or reused because they are not single-use items. We further indicated that hospitals submitting pass-through claims for these devices might be considered to be engaging in fraudulent billing practices (65 FR 67822).

In the proposed rule, we discussed issues that have come to our attention regarding reprocessed single-use devices. We noted that the FDA published guidance for the reprocessing of single-use devices (FDA's ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,'' issued August 14, 2000). This document presents a phased-in regulatory scheme for reprocessed devices. We proposed to follow FDA's guidance on reprocessed single-use devices. We stated that we would consider reprocessed single-use devices that are otherwise eligible for pass-through payment as part of a category of devices to be eligible for that payment if they meet FDA's most recent regulatory criteria on single-use devices. Also, reprocessed devices must meet any FDA guidance or other regulatory requirements in the future regarding single use. We proposed to consider reprocessed devices adhering to these guidelines as having met our criterion of approval or clearance by the FDA. We have met with and will continue to meet and coordinate with the FDA concerning that Federal agency's definition and regulation of single-use devices. We also stated our expectation that hospital charges on claims submitted for pass-through payments for reprocessed single-use devices would reflect the lower cost of these devices.

We received several comments on this proposal, which are summarized below.

Comment: One commenter expressed agreement with our decision to allow hospitals to submit claims for pass-through payment for reprocessed devices, as long as the device is reprocessed in accordance with FDA policy on reprocessing.

Response: We appreciate the comment. It is important to emphasize that, in order to qualify for pass-through payment, a reprocessed device must clearly fit into one of the currently open device categories established for pass-

through payment. We also expect that the charges for the reprocessed device will accurately reflect any lower cost of reprocessed devices.

Comment: One commenter recommended that CMS not expect hospitals to charge less for reprocessed devices, claiming that paying hospitals less for reprocessed devices would perpetuate an incentive to use new devices instead of reprocessed devices.

Response: We disagree. Hospitals would not necessarily have a greater incentive to use new devices if their charges for reprocessed devices are in accordance with their costs. If the charges reflect the lower costs of the reprocessed devices to the hospital, the margins for reprocessed versus new devices should remain relatively constant. This would not create an incentive for hospitals to use either new or reprocessed devices. On the other hand, if hospitals to charge the same amount for reprocessed and original devices, this would inflate the margins of pass-through payment for reprocessed devices and create an incentive to use reprocessed over new devices.

Comment: Several commenters asked that CMS clarify how we will implement and enforce our pass-through payment policy for reprocessed single-use devices. A device manufacturer pointed out that Pre-Market Approval and 510k submissions for approval of reprocessed single-use devices are still pending with the FDA, awaiting final decisions. These commenters also asked how CMS would prohibit noncompliant single-use devices from receiving Medicare payment.

Response: As we indicated in the proposed rule, we will follow the most recent FDA guidance or regulatory criteria on the issue of reprocessed single-use devices. When the FDA requires reprocessors, including hospitals, to have FDA approval or clearance regarding safety and effectiveness, prior to use in a health setting. Hospitals must adhere to these requirements, and will not be entitled to receive a pass-though payment if they do not comply. We will employ our standard procedures for claims reviews to enforce these requirements.

Comment: One commenter recommended that CMS develop and implement a tracking mechanism to differentiate and collect data on reprocessed versus original device costs and use. This commenter also recommended either creating a modifier or establishing pairs of categories for original and reprocessed devices.

Response: Reprocessed devices will be subsumed under the same categories as the original devices, and the average cost for the category will accurately reflect the cost of reprocessed and new devices. We do not believe that it is practical or advisable to create special modifiers or categories for items that will be receiving pass-though payments for only a limited period of time.

Comment: One commenter recommended that CMS provide hospitals with guidance on how to adjust their charges for reprocessed devices eligible for pass-through payment, taking into account the costs of reprocessing and amortization of the initial cost of the device.

Response: We expect those hospitals' charges for reprocessed single-use devices will reflect their costs, just as in the case of the first-use devices. The device's full cost to the hospital is reflected in the payment the first time it is used for a Medicare patient. The cost of the reprocessed device to the hospital will already include the cost of reprocessing. No amortization of the initial cost of the device will apply for single use devices, since they are intended for one time use only.

G. Criteria for New Technology APCs

1. Background

In the April 7, 2000 final rule (68 FR 18477), we created a set of new technology APCs to pay for certain new technology services under the OPPS. New technology APCs are intended to pay for new technology services that are not addressed by the transitional pass-through provisions of the BBRA 1999 and BIPA 2000. New technology APCs are defined on the basis of costs and not the clinical characteristics of a service. The payment rate for each new technology APC is based on the midpoint of a range of costs.

The new technology APCs that were implemented on August 1, 2000 were populated with 11 new technology services. We stated in the April 7, 2000 rule that we will pay for an item or service under a new technology APC for at least 2 years but no more than 3 years, consistent with the term of transitional pass-through payments. After that period of time, during the annual APC update cycle, we stated that we will move the item or service into the existing APC structure based on its clinical attributes and, based on claims data, its resource costs. For a new technology APC, the beneficiary coinsurance is 20 percent of the APC payment rate.

In the April 7, 2000 rule, we specified an application process and the information that must be supplied for us to consider a request for payment under the new technology APCs (65 FR 18478). We also described the five criteria we would use to determine whether a service is eligible for assignment to a new technology APC group. These criteria, which we are currently using, are as follows:

- The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the service could not have been adequately represented in 1996 data.
- The item or service does not qualify for an additional payment under the transitional pass-through payments provided for by section 1833(t)(6) of the Act as a current orphan drug, as a current cancer therapy drug or biological or brachytherapy, as a current radiopharmaceutical drug or biological product, or as a new medical device, drug, or biological.
- The item or service has a HCPCS code.
- The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act.
- The item or service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act.

2. Modifications to the Criteria and Process for Assigning Services to New Technology APCs

Based on the experience we have gained and data we have collected since publication of the April 7, 2000 final rule, we proposed in the August 24 proposed rule to revise—(1) the definition of what is appropriately paid for under the new technology APCs; (2) the criteria for determining whether a service may be paid under the new technology APCs; (3) the information that we will require to determine eligibility for assignment to a new technology APC; and 4) the length of time we will pay for a service in a new technology APC.

We invited comment on the changes to the definition, criteria, application process, and timeframe that we proposed for services and procedures that may qualify for assignment to a new technology APC under the OPPS. We received numerous comments on the proposed changes, primarily from drug and device manufacturers and their trade associations, but also from medical specialty societies and hospital associations. Although several commenters supported the changes that we proposed, most commenters expressed concern that the new requirements might make it extremely difficult or virtually impossible for any new technology to qualify for

assignment to a new technology APC. Many commenters urged us to maintain flexibility in approving services and products for new technology APCs rather than adhering to rigid criteria. The comments are summarized below.

a. Services Paid Under New Technology APCs. We proposed to limit eligibility for placement in new technology APCs to complete services or procedures. That is, items, materials, supplies, apparatuses, instruments, implements, or equipment that are used to accomplish a more comprehensive service or procedure would not be eligible for placement in a new technology APC. Devices or any drug, biologic, radiopharmaceutical, product, or commodity for which payment could be made under the transitional pass-through provisions would continue to be excluded from assignment to a new technology APC. We proposed to limit new technology APCs to comprehensive services or procedures that are truly new. In addition, we clarified that we do not consider a different approach to an existing treatment or procedure to qualify a service for assignment to a new technology APC.

A few commenters supported our proposal to limit eligibility to complete services and procedures, and to exclude changes to an existing service or procedure from new technology APCs. They cited this approach as a means of better controlling and managing payment and improving the predictability of cost estimates for new services or procedures under the OPPS. However, most commenters were opposed to these proposals. (In our responses to comments in this section VI.G., we use ''HCPCS code'' to mean a Level II HCPCS/National Code and ''CPT code'' to mean a Level I HCPCS code.)

Comment: One commenter was concerned that the new criteria for identifying devices that will be eligible for assignment to a new technology APC will make it more difficult for new devices to qualify.

Response: The commenter is correct. The changes that we proposed are intended to clarify, sharpen, and refine the scope of what we assign and pay for under a new technology APC. We want to clarify that new technology APCs are *not* meant to be the payment vehicle for items that can be paid under a transitional pass-through device category. Nor are new technology APCs meant to be a means of paying for drugs, biologicals, or radiopharmaceutical drugs that are otherwise eligible for transitional pass-through payments. The cost of a device that is not eligible for transitional pass-through payment and that is not associated with a comprehensive service or treatment eligible for assignment to a new technology APC will become incorporated into the weight of the APC or APCs associated with its use as hospitals begin to use it. The same is true for other items, supplies, and equipment that are furnished incident to a service or procedure and are used as a tool or serve as an aid in performing a variety of procedures.

Comment: A number of commenters were opposed to limiting new technology APCs to services and procedures that are ''truly new'' because what constitutes ''truly new'' is vague and difficult to define and does not reflect the significant advances in medical technology that are incremental and build on existing technology or procedures. One commenter argued that transformational technology often changes significantly the *way* that a procedure is done, for example, changing a traditionally human resource (for example, labor) or time intensive procedure to one that is technology intensive. Commenters were concerned that the requirement that a new technology be ''truly new'' could result in lack of adequate payment for important new therapies and severely limit patient access to such therapies. For example, a new interventional radiology or other minimally invasive procedure such as the recent advances in endovascular techniques and device technology that replace traditional open surgery could be viewed as a ''different approach to an existing treatment'' and therefore not qualify for assignment to a new technology APC. One commenter concluded that this requirement would limit new technology APCs to inpatient procedures that move to an outpatient setting or procedures that are fundamentally different enough to qualify for a new CPT code. Many commenters recommended that innovation that improves current procedures be recognized and paid for in addition to ''truly new'' services. Several commenters stated that we should publish the definition of ''truly new'' in the **Federal Register** for public comment before implementing this criterion.

Response: In fact, we do want to limit new technology APCs to those services that would be eligible for a new HCPCS code. For example, there are existing codes for wound repair which hospitals have been using to bill for Medicare services for many years. The use of a new, expensive instrument for tissue debridement or a new, expensive wound dressing does not in and of itself warrant creation of a new HCPCS code to describe the instrument or dressing; rather, the existing wound repair code appropriately describes the service that is being furnished, that is, the service is a wound repair, regardless of whether or not a new instrument or a new wound dressing is involved. We would consider it inappropriate to pay for the wound repair performed with the new, expensive dressing or instrument under a new technology APC because an APC group that includes the wound repair procedure already exists. (However, we note that the dressing or instrument could qualify for transitional pass-through payments.) Similarly, the invention of a new endoscope or new suturing material would not qualify for a new technology APC unless the procedure in which it is used cannot be appropriately billed under an existing code.

By contrast, new services such as cryosurgery of the prostate, coronary artery brachytherapy, and 3-D electrophysiologic mapping of the heart are not adequately described with current codes, and they do not fit appropriately within an existing APC group. The new technology APCs are intended to address appropriate payment for these latter types of services, which cannot be accurately described by existing codes and are not similar either clinically or in terms of resource use with an existing APC group.

We want to ensure appropriate allocation of Medicare expenditures and access for our beneficiaries to breakthrough technologies. The appropriate method of reflecting changes in the costs of supplies and equipment used to provide existing services is to incorporate those changes into the payment for such services during the yearly reclassification and recalibration of the APCs. We believe it is appropriate for those new technologies that can be appropriately reported by existing codes and do not qualify for transitional pass-through payments to be grouped with older technologies, and have their costs gradually incorporated into APCs when APC weights are adjusted.

In summary, the most important criterion that will determine whether a technology is ''truly new'' and appropriate for a new technology APC is the inability to appropriately, and without redundancy, describe the new, complete (or comprehensive) service with any combination of existing HCPCS and CPT codes. We acknowledge the need to critically evaluate, on an ongoing basis, our criteria for new technology APCs. We remind interested parties that eligibility

of a procedure for a temporary HCPCS code and assignment to a new technology APC does not guarantee that a permanent code will ultimately be approved for the service or procedure. Conversely, the fact that a new CPT or HCPCS code has been assigned to a service or procedure does not automatically qualify it for placement in a new technology APC unless it meets the criteria we have established for this purpose.

Comment: A few commenters indicated that we need to better define ''complete services or procedures'' and ''a more comprehensive service'' with a clearer explanation of the underlying intent and examples to clarify when assignment to a new technology APC would be appropriate and when it would not. A couple of commenters stated that our proposal to permit only ''complete'' or ''comprehensive'' services or procedures to qualify for assignment to a new technology APC is contrary to the underlying concepts of the OPPS. These commenters argued that hospital outpatient departments, in order to provide a ''complete'' or ''comprehensive'' service, are allowed and expected to bill the appropriate set of CPT and HCPCS codes that combine to describe a particular service, often resulting in claims with multiple codes matched to multiple APCs. The same commenters asserted that a new technology or procedure will likely consist of multiple codes and multiple APCs and that this can be most effectively evaluated as part of the data collection during the period that the technology or procedure is assigned to a new technology APC. One commenter stated that medical technologies, even when considered transformational, are not usually ''complete services and procedures.''

Response: These comments focus on our concept of the type of services appropriate for assignment to new technology APCs under the OPPS. A service that qualifies for a new technology APC may be a complete, stand-alone service (for example, water-induced thermotherapy of the prostate or cryosurgery of the prostate) or it may be a service that would always be billed in combination with other services (for example, coronary artery brachytherapy). In the latter case, the new technology procedure, even though billed in combination with other, previously existing procedures, describes a distinct procedure with a beginning, middle, and end. Drugs, supplies, devices, and equipment in and of themselves are not a distinct procedure with a beginning, middle, and end. Rather, drugs, supplies, devices, and equipment are used in the performance of a procedure. Therefore, taken individually and apart from the procedure or service with which they are used, these items will not be eligible for new technology APCs. (As noted above, these items may qualify for transitional pass-through payments.) Furthermore, unbundled components that are integral to a service or procedure (for example, preparing a patient for surgery or preparation and application of a wound dressing for wound care) are not eligible for consideration for a new technology APC.

We understand that hospitals frequently bill multiple codes to describe multiple services furnished to a given patient. Therefore, we are not making eligibility for new technology APCs contingent on whether hospitals would bill other HCPCS codes in conjunction with a proposed new technology procedure. However, we reiterate that the inability to describe appropriately, and without redundancy, a complete (or comprehensive) service with any combination of current CPT or HCPCS codes is crucial to determining eligibility for a new technology APC. It is possible that a procedure for which assignment to a new technology APC is sought can only be described by several current codes and the applicant believes it is important to establish a single HCPCS code to describe the procedure in a more comprehensive manner (for example, stereotactic radiosurgery or intensity modulated radiotherapy). We agree with this and will consider creating such new HCPCS codes if reporting a combination of current codes does not adequately describe the service or does not properly account for the resources used to deliver the comprehensive service.

In short, we consider that a ''truly new'' service is one that cannot be appropriately described by existing HCPCS codes and that a new HCPCS code needs to be established in order to describe the new procedure.

Claims for services assigned to new technology APCs should include, in addition to other HCPCS codes billed, the appropriate revenue codes and charges for the resources required to deliver the service. We evaluate these data to identify the complete package of resources required to perform the new technology service, the cost of this package of services, and, subsequently, the extent to which the new technology service is, or is not, consistent with services in an existing APC. If, over time, our claims data indicate that the package of resources and the clinical components of the new technology are unique and bear no similarity to services in any existing APC, we may create a separate APC for the new technology service when it is reassigned from a new technology APC. Examples of services that are currently in new technology APCs due to lack of data include water-induced thermotherapy, coronary artery thrombectomy, and coronary artery brachytherapy.

Comment: Several commenters stated that we should eliminate the proposed criteria for defining services eligible for new technology APCs and suggested, instead, that we be flexible and work closely with manufacturers, providers, the APC Panel, and other experts ''to consider circumstances unique to the individual technology'' when determining whether a new technology APC is appropriate.

Response: We will continue to work with manufacturers and their representative associations, with hospitals, with the APC Panel, with other experts, and with applicants as we evaluate requests for new technology APC assignments and determine which are appropriate for new technology APCs. The review of an application for new technology APC assignment by our medical officers and clinical experts is a dynamic, interactive process that involves ongoing consultation with the applicant, with hospitals and physicians who are furnishing the service or who participated in clinical trials, with the manufacturers of the new technology, and with other agencies such as the FDA that may have pertinent information. We believe that the criteria that we proposed serve to inform, guide, and expedite the review process and help to guard against inappropriate assignment of services to a new technology APC simply on the basis of those services being characterized as ''new.''

Comment: One commenter recommended that an applicant be the one to determine whether to seek pass-through payment for a drug used as part of the service or new technology APC status for the entire service, including the drug.

Response: We agree. Application for pass-through payment or new technology APC status is voluntary and the determination of which application(s) to submit is left solely to the interested party. However, as part of the review process, we would expect to work with the applicant to arrive at the most appropriate classification for the service under consideration.

Comment: Several commenters recommended that we further clarify the proposed criteria to ensure that all new technologies and services that do not

qualify for pass-through status and that would not be adequately paid under existing APCs can be assigned to new technology APCs. These commenters also recommended that, when a pass-through category expires, we consider reclassifying medical devices in the expired category into a new technology APC to give beneficiaries seamless access to expensive new medical technology.

Response: As we discussed above, devices eligible for pass-through payments fall outside the scope of services appropriate for new technology APCs. As data associated with pass-through items are collected and incorporated into the APCs with which they are associated, they will be reflected in the weight of the APC. The services assigned to the new technology APCs are those for which we do not have adequate data to make an appropriate APC assignment. Thus, it would not be appropriate to assign a pass-through device for which we have collected data to a new technology APC.

b. Criteria for Assignment to New Technology APC. In the proposed rule, we proposed that the following criteria be used to determine whether a service be assigned to a new technology APC. These proposals represent modifications to criteria that are based on changes in data (we are no longer using 1996 data to set payment rates) and our continuing experience with the system of assigning new technology APCs.

- The service is one that could not have been adequately represented in the claims data being used for the most current annual payment update. (Current criterion based on 1996 data.)
- The service does not qualify for an additional payment under the transitional pass-through provisions. (This criterion is unchanged.)
- The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs. We believe it is unnecessary to assign a new service to a new technology APC if it may be appropriately placed in a current APC. (This criterion for assignment to a new technology APC is implied but not explicitly stated in the April 7, 2000 final rule.)
- The service falls within the scope of Medicare benefits under section 1832(a) of the Act. (This criterion is unchanged.)
- The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. (This criterion is unchanged.)

We further proposed to delete the criterion that the service must have a HCPCS code in order to be assigned to a new technology APC. We wish to clarify that our proposal to delete the criterion that a service must have a HCPCS code refers to the discussion in the April 7, 2000 final rule which implied that assignment of a HCPCS code through the annual HCPCS cycle is required. On the contrary, as we state throughout this section, in order to be considered for a new technology APC, a truly new service cannot be adequately described by existing codes. Therefore, in the absence of an appropriate HCPCS code, we would consider creating a HCPCS code that describes the new technology service. These HCPCS codes would be solely for hospitals to use when billing under the OPPS.

Most commenters supported the proposal not to require a HCPCS code for products or services in order to be considered for assignment to a new technology APC. The few commenters that addressed the proposed criterion that would define a new technology APC service as one that could not have been adequately represented in the claims data being used for the most current annual payment update (rather than on 1996 claims data) concurred with the proposed change; no one opposed the change. The remaining comments on these proposed criteria are summarized below.

Comment: One commenter wanted to confirm our intention to assign a new service or procedure to an existing APC only in those instances where a clinically similar APC exists and the associated APC payment rate meets or exceeds the cost of furnishing the new technology service as itemized in the application for a new technology APC.

Response: Our experience to date in evaluating requests for new technology APC classification prompted us to propose changes regarding the information that would be required in an application. One of the principal reasons that we proposed to require submission of a clinical vignette, including a detailed description of the resources used to furnish the service, was to enable us to determine whether a clinically similar APC exists and whether the APC payment rate adequately addresses the costs associated with the nominated new technology service. However, we will not limit our determination of the cost of the procedure to information submitted by the applicant. Our staff will obtain information on cost from other appropriate sources before making a determination of the cost of the procedure to hospitals.

Comment: A number of commenters strongly opposed the criterion excluding any service involving a new drug or biological that qualifies for transitional pass-through payment from possible eligibility as a new technology APC. Commenters stated that continuing to exclude drugs or biologicals eligible for pass-through payments from being eligible for a new technology APC seems to suggest that an entirely new service that includes a new drug would only be eligible for pass-through payments for the drug, rather than the entire service being eligible for payment under a new technology APC. Under this criterion, novel treatments such as those in the growing field of radioimmunotherapy that involve both a new drug and new procedures for both calculating appropriate dosages and administering treatment would not be paid as a new technology APC. Instead, the hospital would be paid for the cost of the drug through the applicable pass-through payment, which may result in underpaying hospitals for the total package of items and services associated with the treatment.

Commenters requested that we clarify that a brand new service in which a pass-through drug or device is used could be eligible for either a pass-through payment for the drug or device or for a new technology APC for the entire service and that we permit a new technology that includes the provision of a new drug or biological to be eligible for payments under a new technology APC. A few commenters recommended that we eliminate this requirement altogether and allow new medical device technology to be included in new tech APCs.

Response: In the April 7, 2000 final rule we adopted a criterion that provided that an item or service that qualifies as a transitional pass-through item would not be considered for assignment to a new technology APC. We proposed to retain that criterion without modification. We have *never* intended new technology APCs to be a substitute payment vehicle for individual items that qualify for payment under a transitional pass-through device category. Nor are new technology APCs meant to be the means of payment for drugs, biologicals, or radiopharmaceutical drugs that are otherwise eligible for transitional pass-through payments. From the outset of the OPPS, our policy regarding payment for devices, drugs, and biologicals that do not qualify for transitional pass-through payment has been to package payment with the items' associated APCs, with the exception of a few drugs for which we had insufficient data.

Many commenters expressed concern and disagreement with this criterion. We believe the commenters misunderstood our explanation of this

criterion. Therefore, we reiterate that we have never intended to disqualify from assignment to a new technology APC a truly new, comprehensive service, procedure, or therapy that involves the use of a drug or device which, on its own, might also qualify for a transitional pass-through payment. That is, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment.

Take, for example, a case in which a drug that qualifies for a pass-through payment is integral to a service that may be considered a new, comprehensive procedure or service appropriate for a new technology APC. In this case, an interested party has several options. The first option is to simply submit a request for the drug pass-through payment. Under this option, the therapy or procedure or service associated with administration of the drug would be paid through an existing APC that most closely approximates the service clinically and in terms of resources. (In this option, if the new service associated with the drug can be appropriately described by one or more existing HCPCS codes, it is possible that the new service might not qualify for a new technology APC.) A second option would be for the interested party to apply for a pass-through payment for the drug and submit a separate application for assignment of the therapy or procedure associated with administration of the drug to a new technology APC. A third option is to submit an application to have the *entire* service, *including* the potential pass-through drug, which is an integral part of the service, assigned to a new technology APC. In that case, the cost of the drug would be taken into account and packaged with the other costs associated with the service so that the drug cost is reflected and accounted for within the new technology APC payment rate for the service. We believe the third option represents a simple, unburdensome approach that would ensure timely and appropriate payment in a new technology APC for a new service that includes administration of a new drug or biological and that meets the other criteria for a new technology APC. For both options two and three, we would first consider whether assigning a new HCPCS code is appropriate and, if it is, we would then determine whether the new code should be assigned to an existing APC. If not, we would assign it to a new technology APC.

c. Revision of Application for New Technology Status. In the August 24 proposed rule we proposed to change the information that interested parties must submit to have a service or procedure considered for assignment to a new technology APC. Specifically, to be considered, we proposed to require that requests include the following information:

- The name by which the service is most commonly known. We currently require only the trade/brand name.
- A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services as well as equipment, supplies, and devices, etc. This criterion would replace the criterion that requires a detailed description of the clinical application of the service.
- A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained.
- A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location.
- An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.
- Information about the clinical use and efficacy of the service such as peer-reviewed articles.
- The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS.
- A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for new technology status, would represent unbundling.
- A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.
- A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate.
- An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc. (This criterion is unchanged.)
- The name, address, and telephone number of the party making the request. (This criterion is unchanged.)
- Other information as CMS may require to evaluate specific requests. (This criterion is unchanged.)

One commenter stated that, on the whole, the proposed changes to the information that interested parties must submit to have a service or procedures considered for assignment to a new technology APC seem reasonable and designed to minimize the need for time-consuming requests for supplemental information from applicants. Other comments on the proposed changes are summarized below.

Comment: A few commenters stated that the significant amount of additional data required to file an application is unnecessarily burdensome, and, in some cases, may not be available when new products are launched. In particular, one commenter was concerned that the information needed to provide a clinical vignette (patient diagnoses that the service is intended to treat, the typical patient, a description of resources used to furnish the service such as staff, equipment, supplies, and similar facility and professional resources) may not always be available when a new product is launched. The commenter was also concerned that upcoming implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will make providers reluctant to furnish necessary data to manufacturers. The need for consent releases and storage retention required by the HIPAA regulations are added administrative costs that will have to be incurred. Instead, the commenter recommended that we request a detailed description of the service which, if possible, includes the resources used during the procedure.

Response: Our experience with new technology applications has revealed the critical need for the information on clinical factors and resource utilization that is described as part of a ''clinical vignette.'' Without this information, it is difficult to understand what the nominated service involves in both clinical and resource terms. We need the fullest possible description of every aspect of the service to help us understand how it is being furnished in hospitals and the costs associated with the service. This information is indispensable in assessing the appropriate payment rate for the

nominated service. We believe that those seeking to apply for new technology APC status for a service will have sufficient expertise and experience with the service to enable them to furnish the full and detailed description of the service that is required as part of the clinical vignette. Based on our experience to date in reviewing applications for new technology APCs, there is strong evidence that close cooperative working relationships exist among manufacturers, hospitals, and clinicians who seek to have a service assigned to a new technology APC. When we have had to ask for additional information of the type we proposed to require for future applications, this information has been readily available and promptly supplied.

Comment: One commenter stated that the requirement for ''a description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location'' appears excessive if all that is sought through this requirement is the identification of medical contacts. A commenter expressed concern that having to identify all facilities or physicians performing the procedure would in many cases appear to be administratively excessive and a potential breach of confidentiality. A commenter recommended that, if medical contacts are desired, the requirement should be for the names, contact information and approximate number of patients treated for a ''representative'' sample of facilities and/or physicians performing the procedure or service who are willing to serve as such contacts.

Response: While this requirement would furnish us with medical contacts, it also provides us with other significant information. For example, knowing the locations where the service is being performed and the approximate number of patients receiving the service provides insight into the extent to which the service is being performed (rarely, occasionally, or frequently); the types of hospitals where it is being performed (small rural or suburban hospitals, large urban teaching hospitals); and a geographic profile of where the service is currently available. We believe it is crucial to our evaluation of nominated procedures that we have a detailed understanding of, among other things, the indications and contraindications for the procedure, the current utilization of the procedure, the patient populations for which the procedure is performed, the types of hospitals where it is performed, the sites (for example, inpatient hospital, physician office) and locations (for example, teaching hospitals, community hospitals) where the procedure is performed. Without such information, we cannot make an appropriate determination as to whether the procedure is ''truly new''. This information, along with information about the specialties of physicians performing the service, assists our medical advisors and clinicians in their evaluation of whether or not the service should be assigned to a new technology APC.

Comment: One commenter wanted assurance that ''information about the clinical use and efficacy of the service such as peer-reviewed articles' would be referred to the Office of Clinical Standards and Quality if the intent of this new requirement were to determine whether the new technology should be ''covered.''

Response: The purpose of this requirement is to help us better understand the clinical dimensions of the service. Neither assignment of one or more new HCPCS code(s) to a procedure or assignment of a procedure to a new technology APC assures that Medicare will cover the procedure. In order for a procedure to be covered by Medicare, it must be determined, either locally, or nationally, that the procedure is medically reasonable and necessary. Information about how to obtain a national coverage decision is posted on the CMS website at http://www.hcfa.gov/coverage. To receive Medicare payment, services must be considered reasonable and necessary and each use of a service is subject to medical review for determination of whether its use was reasonable and necessary.

d. Length of Time in a New Technology APC. We proposed to change the period of time during which a service may be paid under a new technology APC. We noted that although section 1833(t)(6)(B) of the Act, as amended by section 201 of BBRA 1999, sets a 2 to 3 year period of payment for transitional pass-through payments, this requirement does not extend to new technology APCs. We proposed to modify the time frame that we established for new technology APCs in the April 7, 2000 final rule and to retain a service within a new technology APC group until we have acquired adequate data that allow us to assign the service to a clinically appropriate APC. This policy would allow us to move a service from a new technology APC in less than 2 years if sufficient data were available and would also allow us to retain a service in a new technology APC for more than 3 years if sufficient data upon which to base a decision had not been collected.

Comment: One commenter supported eliminating the 2 to 3 year assignment to a new tech APC, which would give CMS greater flexibility to base future payment on adequate pricing data that could take less than 2 or more than 3 years to collect.

Several commenters stated that we should clarify at the time of the assignment to the new technology APC how the decision will be made to move it into a permanent APC. Specifically, these commenters indicated that we should publish the methodology used to reassign services from new technology APCs into existing APC categories, including how we will evaluate clinical and cost data to determine whether or not a service in a new technology APC should be reassigned to an existing APC.

Most commenters supported keeping a procedure in a new technology APC for a minimum of 2 years of data collection to ensure that an adequate claims database is available to make appropriate decisions about ultimate APC assignment, structuring, packaging, and payment. These commenters noted that limited procedure volume and coding confusion immediately following market release of a new technology could limit the amount of useful data that would be available in the first year.

Response: We agree with commenters that adequate claims data is more important than completion of a fixed time span for determining when to reassign a new technology APC service. We expect that, practically speaking, we will need a full year of available claims data. We use the same methodology to reassign services from a new technology APC to an existing APC group, or to a new APC group if that is indicated, that we use in our annual review of all APC weights and assignments. That is, we review claims-based charge and utilization data and the most recent available cost report data. This process may include consulting the APC Advisory Panel for its recommendations regarding appropriate APC assignments.

Comment: Several commenters urged us not to reassign new medical procedures from one new technology APC to another during the yearly updates to the APC system absent current and complete data. These commenters asserted that during the period when a new procedure is assigned to a new technology APC, there may be reasons why claims data used for the annual updates to the APC system are not representative of actual hospital experience in providing the service. Therefore, we should recognize that the reasons that support a multi-

year assignment to a new technology APC, that is, the need to gather data, also argue for caution in moving services from one new technology APC (and payment rate) to another.

Response: In general, we agree that once a device has been assigned to a new technology APC, it will remain there until we have collected the data necessary to move it to a clinically appropriate APC. However, we have on occasion, made an assignment to a new technology APC based on information that later was found to have been inaccurate. In those cases, we believe that it is appropriate to move the service to the new technology APC that better reflects the cost. We note that when we have made these changes in the past, services were moved to higher-paying APCs as well as lower-paying APCs.

Comment: One commenter urged that any new criteria that we adopt be applied prospectively to those applications submitted after the effective date of the final rules.

Response: Changes in the criteria and application process for assigning services to a new technology APC will be made prospectively, effective upon implementation of this final rule.

Comment: Although the new technology APCs and pass-through device categories were to be updated on a quarterly basis, many applications have taken much longer to process. CMS should establish a mechanism to process applications in a timely manner. One commenter suggested monthly updates.

Response: The volume of applications and changes we have had to make in the OPPS following enactment of BIPA have combined to stretch our resources to the maximum. Also, the need to seek additional information to enable us to complete a thorough and rigorous evaluation of applications for new technology APC assignments has often caused delays in making a final determination. We believe the additional information that we proposed to require in an application for new technology APC status will assist us in completing our reviews and making final determinations in a timely manner. CMS and our fiscal intermediaries' systems constraints preclude making updates more frequently than quarterly.

Comment: One commenter stated that the amount of information provided in the proposed rule does not satisfy the requirement of the Administrative Procedures Act that the public be informed and allowed to comment on major regulatory changes. The commenter requested full disclosure of data, methodology and options considered prior to implementation of the methodology with a suitable time of at least 60 days for public comment. The commenter requested that we retain the criteria established in the April 2000 final rule but that we eliminate the need for a HCPCS code.

Response: We believe that our description of the proposed changes to the criteria and application process for new technology APCs allowed ample opportunity for substantive comment, and we did receive numerous substantive comments on the proposed changes. In addition, changes in the process and information required to apply for new technology APC status under the OPPS are subject to provisions of the Paperwork Reduction Act (PRA) of 1995, as further explained in section XII of this final rule.

Final Action: We are making final the changes we proposed regarding the definition of what is appropriately paid for under a new technology APC, the criteria for determining assignment to a new APC, the information that must be supplied for a request to be considered, and the period of time during which payment in a new technology APC can be made. The schedule for submission of applications and the process and information required for a new technology APC designation is posted on the CMS website at http://www.hcfa.gov/medlearn.

VII. Transitional Pass-Through Payment Issues

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain innovative medical devices, drugs, and biologicals. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also required for new medical devices, drugs, and biologic agents that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments are to be made for at least 2 years but not more than 3 years.

Section 402 of BIPA, which was enacted on December 21, 2000, made several changes to section 1833(t)(6) of the Act. First, section 1833(t)(6)(B)(i) of the Act, as amended, requires us to establish by April 1, 2001, initial categories to be used for purposes of determining which medical devices are eligible for transitional pass-through payments. We fulfilled this requirement through the issuance on March 22, 2001 of two Program Memoranda, Transmittals A–01–40 and A–01–41. These Program Memoranda can be found on the CMS homepage at *www.hcfa.gov/pubforms/transmit/A0140.pdf* and *www.hcfa.gov/pubforms/transmit/A0141.pdf,* respectively. We note that section 1833(t)(6)(B)(i)(II) of the Act explicitly authorizes the Secretary to establish initial categories by program memorandum.

Transmittal A–01–41 includes a list of the initial device categories and a crosswalk of all the item-specific C-codes for individual devices that were approved for transitional pass-through payments as of January 20, 2001 to the initial category code by which the device is to be billed beginning April 1, 2001.

Section 1833(t)(6)(B)(ii) of the Act also requires us to establish, through rulemaking, criteria that will be used to create additional categories, other than those established initially. On November 2, 2001, we published an interim final rule with comment that established the criteria for new categories (66 FR 55850).

Transitional pass-through categories are for devices only; they do not apply to drugs or biologicals. The regulations governing transitional pass-through payments for eligible drugs and biologicals remain unchanged. The process to apply for transitional pass-through payment for eligible drugs and biological agents, including radiopharmaceuticals, can be found in the April 7, 2000 **Federal Register** (65 FR 18481) and on the CMS web site at *http://www.hcfa.gov/medlearn/appdead.htm.* If we revise the application instructions in any way, we will post the revisions on our web site and submit the changes for the Office of Management and Budget (OMB) review under the Paperwork Reduction Act. The application process for new categories can be found on the CMS web site at http://www.hcfa.gov//medicare/newcatapp1030f.rtf.

B. Discussion of Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an ''applicable percentage'' of projected total payments under the hospital OPPS. For a year before 2004,

the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is specified by the Secretary up to 2.0 percent. If the Secretary estimates before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a (prospective) uniform reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded.

As discussed above, on November 2, 2001, we published a final rule that announced the implementation of a pro rata reduction for CY 2002. That document describes the methodology for estimating pass-through payments and indicates that we expected the reduction would be between 65 and 70 percent. Based on the final APC weights, which incorporate 75 percent of the estimated device pass-through costs, the final pro rata reduction is 68.9 percent.

C. Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

As discussed in the proposed rule, in the November 13, 2000 interim final rule (65 FR 67806 and 67825), we had excluded costs in revenue codes 274 (Prosthetic/orthotic devices), 275 (Pacemaker), and 278 (Other implants) from the calculation of APC payment rates. This was because, before enactment of the BBRA 1999, we had proposed to pay for implantable devices outside of the OPPS. After the enactment of the BBRA, it was not feasible to revise our database to include these revenue codes in developing the April 7, 2000 final rule. We were able to make the necessary revisions and adjustments in time for implementation on January 1, 2001. When we packaged costs from these revenue codes to recalculate APC rates for 2001, to comply with the BBRA 1999 requirement, the median costs for a handful of procedures related to pacemakers and neurostimulators significantly increased. Therefore, we restructured the affected APCs to account for these changes in procedure level median costs.

Under section 1833(t)(6)(D)(ii) of the Act, as added by the BBRA 1999 and redesignated by BIPA, the amount of additional payment for an eligible device is the amount by which the hospital's cost exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. Thus, beginning January 1, 2001, for eligible devices, we deducted from transitional pass-through payments the dollar increase in the rates for the new APCs for procedures associated with the devices. Effective April 1, 2001, we revised our policy to subtract the dollar amount from the otherwise applicable pass-through payment for each category of device. The dollar amount subtracted in 2001 from transitional pass-through payments for affected categories of devices is as follows:

TABLE 4.—CY 2001 REDUCTIONS TO PASS-THROUGH PAYMENTS TO OFFSET DEVICE-RELATED COSTS PACKAGED IN ASSOCIATED APC GROUPS

For item billed under HCPCS code. * * *	Subtract from the pass-through payment the following amount:
C1767 Generator, neurostimulator (implantable)	$643.73
C1778 Lead, neurostimulator (implantable)	501.27
C1785 Pacemaker, dual chamber, rate-responsive (implantable)	2,843.00
C1786 Pacemaker, single chamber, rate-responsive (implantable)	2,843.00
C1816 Receiver and/or transmitter, neurostimulator (implantable)	537.83
C2619 Pacemaker, dual chamber, non rate-responsive (implantable)	2,843.00
C2620 Pacemaker, single chamber, non rate-responsive (implantable)	2,843.00

The increase in certain APC rates for device costs on January 1, 2001 was offset by the simultaneous reduction of the associated pass-through payments. Payments for the procedures in the affected APCs that did not include a pass-through device increased for 2001 and for procedures that did include devices, total payment for the procedure plus the device or devices did not change.

For 2002, we estimated in the proposed rule the portion of each APC rate that could reasonably be attributed to the cost of associated devices that are eligible for pass-through payments. This amount will be deducted from the pass-through payments for those devices as required by the statute. Since the deductions to the pass-through payments for costs included in APCs for 2002 are included in the recalibration of the weights and the ''fixed pool'' of dollars for outpatient services, the total payment for the procedure plus device or devices will be reduced rather than remain constant as they did in 2001.

We described our methodology for calculating these reductions for the proposed rule. First, we reviewed the APCs to determine which of them contained services that are associated with a category of devices eligible for a transitional pass-through payment. We then estimated the portion of the costs in those APCs that could reasonably be attributed to the cost of pass-through devices as follows:

- For each procedure associated with a pass-through device or devices, we examined all single-service bills (that is, bills that include services payable only under one APC) to determine utilization patterns for specific revenue centers that would reasonably be used for device-related charges in revenue codes 272 (sterile supplies), 275 (pacemakers), and 278 (other implants).
- We removed the costs in those revenue codes to calculate a cost for the bill net of device-related costs (reduced cost). For example, the average bill cost (in 1999–2000 dollars) for insertion of a cardiac pacemaker (CPT 33208) was $5,733. The average cost associated with revenue code 275 was $4,163, so the reduced cost for the procedure was $1,570. We calculated the ratio of the reduced cost ($1,570) to the full bill costs ($5,733), and we applied that ratio to the costs on any bills for CPT 33208 that did not use revenue code 275 to establish reduced cost at the procedure code level across all claims.
- To determine the reduced cost at the APC level and that portion of the APC payment rate associated with device costs, we calculated the median cost of the reduced cost bills for each relevant APC. For this calculation of the median, we allowed the full costs of bills for services in the APC that were not associated with pass-through devices.
- We calculated, for the APC, the percentage difference between the APC median of full cost or unreduced bills and the APC median where some or all of the bills had reduced costs. We applied this percent difference to the proposed APC payment rate in order to calculate the share of that rate attributable to the device or devices associated with procedures in the APC.

In column 3 of Table 5, we show the amount of the offset that we have computed with this methodology for each of the 25 APCs that we determined to have device costs represented in their rates. We note that the list of 25 APCs with device costs in their rates has changed slightly since the publication of the proposed rule. Specifically, APC 0185, Removal or Repair of Penile